POINT OF CARE
TESTING

CoaguChek® XS Plus

Operator's Manual

Roche

CoaguChek® XS Plus

Operator's Manual

0 5021464001 (05) 2012-05 USA

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On the packaging and on the identification plate of the instrument you may encounter the following symbols, shown here with their meaning:

Caution, consult accompanying documents. Refer to safety-related notes in the instructions for use accompanying this product.

Temperature limitation (Store at)

Use by

Manufacturer

Batch code/ Lot number

Catalog number

In vitro diagnostic medical device

This product fulfills the requirements of the European Directive 98/79/EC on *in vitro* diagnostic medical devices.

Consult instructions for use

The system fulfills the Canadian and U.S. safety requirements (UL LISTED, in accordance with UL 61010A-1:02 and CAN/CSA-C22.2 No. 61010-1-04).

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Manual version	Revision date	Changes
05021464001 (01)	June 2009	New document
05021464001 (02)	November 2009	Revised for new firmware, claims changes, and new cleaning recommendations
05021464001 (03)	May 2010	Revised for CLIA waiver
05021464001 (04)	August 2010	Revised for CLIA waiver re submission
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1 Introduction

Before you start

Intended use

The CoaguChek® XS Plus is intended for use by professional healthcare providers for quantitative prothrombin time testing for the monitoring of warfarin therapy. The system uses fresh capillary or non-anticoagulated venous whole blood.

Important information regarding use

Read this operator's manual, as well as the package inserts for all relevant consumables, before using the system for the first time.

You must configure the CoaguChek XS Plus meter according to your needs before initial use. Refer to chapter 4 *Meter Setup*. Be sure to read the *Important safety instructions and additional information* section in this chapter before operating the system.

Before you use the meter for the first time (after you have first inserted the batteries), you must set the date and time correctly to allow you to perform measurements properly. Each time you replace the batteries you need to check (and, if necessary adjust) the date and time.

If you need help

Information about using the system, the screen menus, and performing a test can be found in this manual.

When error messages appear on the screen, refer to chapter 10 *Troubleshooting*.

For all questions about the CoaguChek XS Plus system that are not answered in this manual, contact your Roche representative or Roche Diagnostics Technical Service. In order to expedite troubleshooting, please have ready your CoaguChek XS Plus meter, its serial number, this manual, and all related consumables when you call.

General note

The data and information provided in this manual are current as of issue. Any substantial changes will be incorporated in the next edition. If there is any conflict of information, the package insert included with the CoaguChek XS PT Test strips shall prevail.

What can the system do for you?

The CoaguChek XS Plus system makes coagulation testing easy. You only need to insert the code chip, power the meter on, insert the test strip, and apply a small blood sample. The blood mixes with the reagents on the test strip, and the meter determines when the blood clots. The meter displays the results in about one minute. After the measurement, the meter automatically stores the test result, together with date/time and patient ID (and operator ID, if that option is enabled) to memory.

The CoaguChek XS Plus meter displays test results in units equivalent to laboratory plasma measurements. Results may be displayed in three ways:

- International Normalized Ratio (INR)
- combination of INR/seconds, or
- combination of INR/%Quick

INR is a standardized measurement of the rate at which blood clots. A low INR can indicate an increased risk of blood clots, while an elevated INR can indicate increased risk of bleeding.

The meter guides you through the test, step by step, using icons and instructions on the display. Each box of test strips has its own code chip that you insert into the meter. This code chip contains lot-specific information about its test strips, such as the expiration date and calibration data. Optional liquid controls for the system are also available.

The CoaguChek XS Plus meter has the ability to connect to a data management system (DMS) through the Handheld Base Unit from Roche (available separately). The CoaguChek XS Plus meter supports data exchange via the POCT1A standard. Data management systems may have the ability to expand the security features of the meter, such as enabling operator lockouts. Data management systems may also enable data transfer to an LIS or HIS. Refer to the manuals of the Handheld Base Unit and of your DMS for technical details.

Test principle

The CoaguChek XS PT Test, used as directed with the CoaguChek XS Plus meter, will provide an electrochemical measurement of prothrombin time following activation of blood coagulation with human recombinant thromboplastin. In simple terms, blood works with the chemicals in the test strip to make a small electric current in the test strip that measures blood-clotting time.

Important safety instructions and additional information

This section explains how safety-related messages and information related to the proper handling of the system are presented in the CoaguChek XS Plus Operator's Manual. Read these passages carefully.

The safety alert symbol alone (without a signal word) promotes awareness to hazards which are generic or directs the reader to related safety information.

These symbols and signal words are used for specific hazards:

WARNING

WARNING
Indicates a hazardous situation which, if not avoided, could result in death or serious injury.

CAUTION

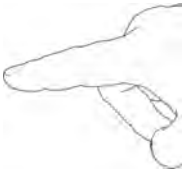
CAUTION
Indicates a hazardous situation which, if not avoided, could result in minor or moderate injury.

NOTICE

NOTICE
Indicates a hazardous situation which, if not avoided, may result in damage to the system.

Important information that is not safety relevant is presented against a colored background (without a symbol). Here you will find additional information on correct use of the meter or useful tips.

Illustrations in this manual show two different kinds of hands:



Hand without glove

Hand with glove

A dashed arrow between screen illustrations indicates that some screens have been skipped in these illustrations.

Safety Information

Operator qualification

Only trained healthcare professionals may operate the CoaguChek XS Plus system. Operators must have received comprehensive instruction in the operation, quality control, and care of the CoaguChek XS Plus system.

WARNING

Protection against infection

There is a potential risk of infection. Healthcare professionals using the CoaguChek XS Plus system must be aware that any object coming into contact with human blood is a potential source of infection. Healthcare professionals must also be aware that any cross-contamination is a potential source of infection for patients.

- Use gloves.
- Use an auto-disabling single-use lancing device for each patient.
- Dispose of used lancets and needles in a sturdy sharps container with lid.
- Dispose of used test strips according to your institution's infection control policy.
- Follow all health and safety regulations in force locally.

Disposal of the System

WARNING

Any product coming in contact with blood is considered contaminated (potentially infectious).*
During normal testing, any meter may come in contact with blood. Lancing devices may also be considered sharps. Disposal of sharps is regulated by law in many jurisdictions.
The European Union has a requirement for improving waster management practices for certain electronic equipment, but meters fall outside the scope of the European Directive 2002/96/EC** This is not a requirement for the U.S.A.; however, Roche is committed to recycling and sustainability. Comply with any laws or ordinances relating to the disposal of sharps and/or contaminated products. Contact your local health department or other appropriate authorities for proper handling and disposal of used meters, used test strips, used lancets, and used batteries. Please consider the following points when disposing of your used testing materials:.

Consider recycling of the meters and batteries at an appropriate facility. Be aware the meter is potentially hazardous electronics scrap (e-scrap) and should be disposed of accordingly. The batteries are potentially hazardous also and should be disposed of accordingly.

Disinfect the meter before recycling or disposing.

*29 CFR 1910.1030 - Bloodborne pathogens

**Directive 2002/96/EC - Directive on waste electrical and electronic equipment (WEEE)

WARNING

Exploding batteries
Do not throw used batteries into an open fire. They may explode.

Disposal of used batteries
Do not dispose of the batteries with normal domestic waste. Dispose of used batteries in an environmentally responsible manner and in accordance with applicable local regulations and directives. Contact your local council/local authority or the manufacturer of the used batteries for advice on correct disposal.

General Care

NOTICE

Clean the meter only with the solutions recommended (see page 119). Using other solutions may result in incorrect operation and possible system failure. Do not let cleaning solution enter the instrument. Make sure that the meter is thoroughly dried after cleaning or disinfecting.

Electromagnetic Interference

Do not use the meter near strong electromagnetic fields, which could interfere with the proper operation of the meter.

Touchscreen

NOTICE

- Use only your finger (even when wearing gloves) or special pens designed for use with touchscreens to touch the screen elements. Using pointed or sharp-edged objects can damage the touchscreen.
- Avoid prolonged exposure to direct sunlight. Direct sunlight may reduce the life expectancy and functionality of the display.

Operating conditions

To ensure that the meter functions properly, please observe the following guidelines:

- Only use the meter at a room temperature between 15 °C and 32 °C (59 °F and 90 °F).
- Only use the meter at a relative humidity between 10% and 85% (no condensation).
- When operating the meter using the power adapter, use only a voltage of 100 V to 240 V (± 10%) , 50/60 Hz.
- When testing, place the meter on a level, vibration-free surface, or hold it so it is roughly horizontal.

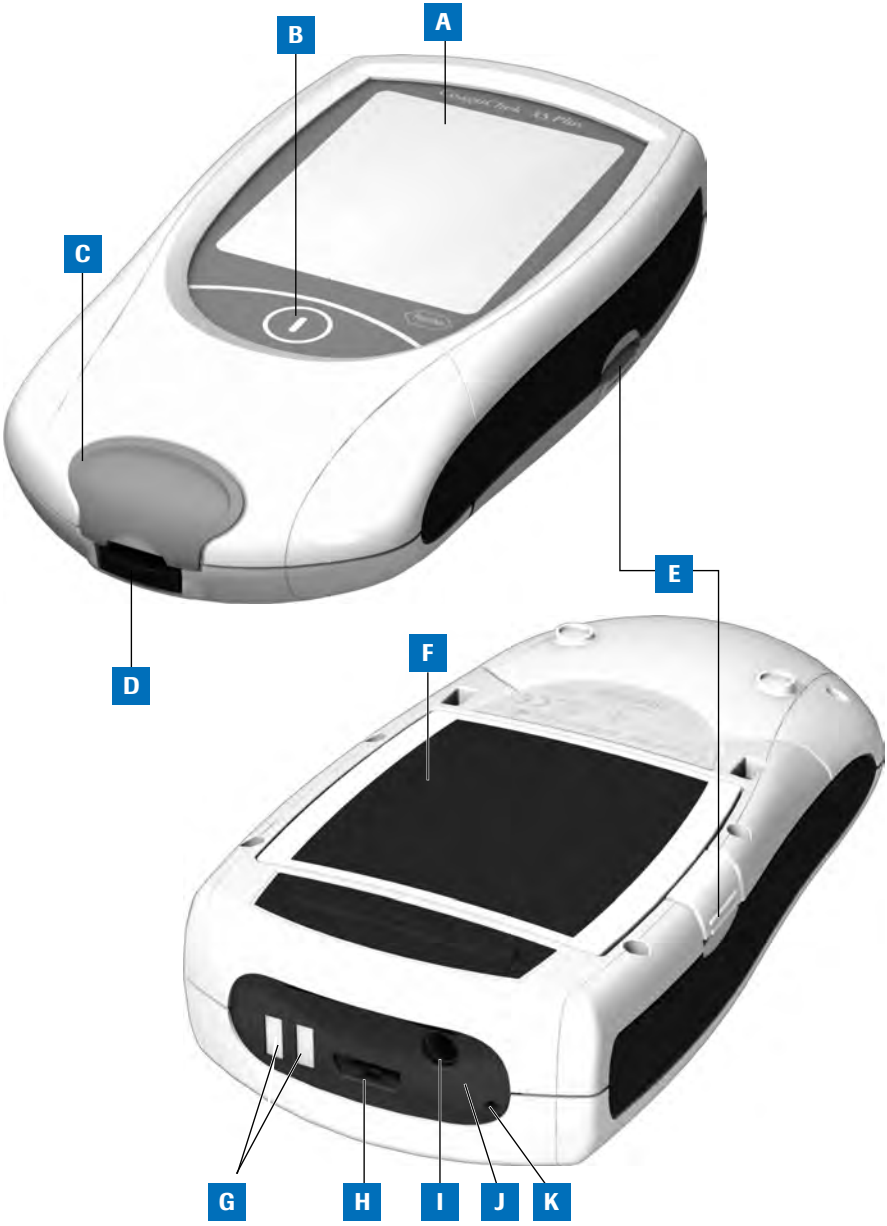
Quality control

The meter has a number of built-in quality-control functions:

- A check of the electronic components and functions every time the meter is powered on.
- A check of the test strip temperature while a test is in progress.
- A check of the expiration date and lot information on the test strip based on the code chip data.
- A two-level, onboard quality control test and patient result determination within a single test chamber.

Roche Diagnostics has available optional liquid quality controls for the CoaguChek XS Plus system. These controls are provided to assist with meeting regulatory compliance requirements as applicable to your facility.

2 The CoaguChek XS Plus Meter



Overview of the meter elements

A **Touchscreen**
Shows test results, information, icons, and results recalled from memory. To select an option, simply touch the button lightly.

B **On/Off button**
Press and hold this button to power the meter on or off.

C **Test strip guide cover**
Remove this cover to clean the test strip guide (if it has become soiled, e.g., with blood).

D **Test strip guide**
Insert the test strip here.

E **Tab for battery compartment cover**

F **Battery compartment cover**
Covers the battery compartment (4 standard AA alkali-manganese batteries or the rechargeable battery pack).

G **Charging terminals**
Used for power supply and/or charging the battery pack, when the meter is docked in the (optional) Handheld Base Unit.

H **Code chip slot**
Insert the code chip here.

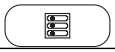
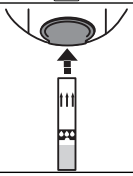
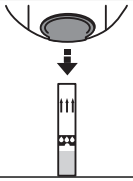
I **Connection socket for power adapter**
Plug in the power adapter here.

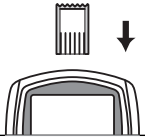
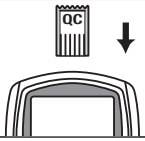
J **Infrared interface**
(Covered by the semi-transparent panel)
Supports data communication.

K **Reset button**
Use this button to reset the meter in case of software or power-up errors.

Buttons and icons overview

The buttons and icons that appear during normal operation are shown here, along with their respective meanings. Error messages and the description of the icons linked to them are provided in a separate chapter. See *Troubleshooting* starting on page 123.

Button/Icon	Meaning
	Go to Main Menu
	OK; save setting
	Cancel; discard setting
	Return (to previous menu)
	Reduce/increase the value displayed. Scroll through lists that are too long to be displayed all at once.
	Inactive button: Value cannot be further decreased/increased or: End of list in this direction is reached
	List of tests of a specific patient
	Print after test result or from memory
	Add a comment
	Operator must wait until the meter has completed an action
	Insert test strip
	Remove test strip
	Apply sample (the time left to apply sample is counted down in the display)

Button/Icon	Meaning
	Apply liquid control (QC) sample (the time left to apply sample is counted down in the display)
	Insert the test strip code chip
	Insert the QC code chip
QC ✓	Automatic quality control completed successfully
%Q	Results are displayed as a Quick percentage value
Sec	Results are displayed in seconds
INR	Results are displayed in INR units
>	Result in the chosen unit of measure is above the measuring range.
<	Result in the chosen unit of measure is below the measuring range.
	Quality control: Result is above the specified range Quality control: Result is below the specified range
	Battery status: • When the batteries still have their full charge, all segments are lit. • Individual segments disappear one by one as the batteries become weaker. • When there is no segment remaining, you can no longer perform a test. You can, however, still access the meter's memory.
	Operation with power supply adapter
am	Time between midnight and noon (in 12-hour time format)
pm	Time between noon and midnight (in 12-hour time format)
	Room or meter temperature is outside the acceptable range

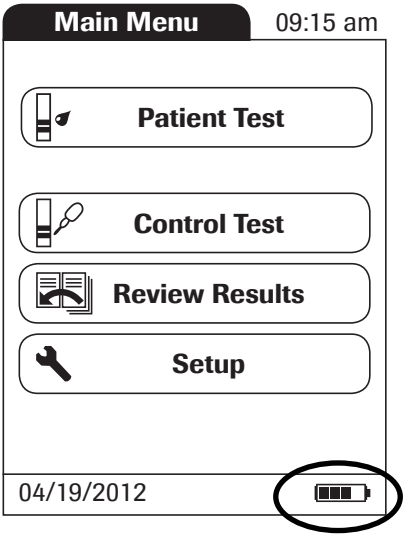
Button/Icon	Meaning
	The test strip guide cover is open
	Communication is taking place via the infrared interface
	Reports a status message (see: Chapter 10 *Troubleshooting*)
	Reports an error message or a warning (see: Chapter 10 *Troubleshooting*)

Power supply

The CoaguChek XS Plus meter can be operated with either the power adapter provided, four standard type AA alkaline, non-rechargeable batteries, or a special rechargeable battery pack (optional). Insert the batteries or the optional rechargeable battery pack even when you use the power adapter. This ensures that you will not lose the date and time settings if the power goes out.

> The power adapter also serves as a charger if you use it with the special rechargeable battery pack.

To save power, the CoaguChek XS Plus meter has the option to automatically power itself off based on your setup selections, unless a button has been pressed or a new test strip has been inserted. The default setting is set to 5 minutes. When the meter powers itself off, all results obtained up to that point remain in memory and the settings will still be there when you power the meter back on. (Refer to *Auto Off* on page 52.)



During battery operation, the meter always displays the battery power level.

When **replacing the batteries or the rechargeable battery pack**, you must insert the new batteries or battery pack within ten (10) minutes of removing the old one(s) to retain the date and time settings. If you take longer than this, you must re-enter the date and time.

To make sure you do not lose your date and time settings, connect the power adapter while you change the batteries or handheld battery pack.

The meter retains results in memory even when no batteries are inserted. All settings other than date and time (deleted after 10 minutes without power) are retained as well.

⚠

Dispose of used batteries and battery packs in an environmentally responsible manner in accordance with applicable local regulations and directives. See *Any product coming in contact with blood is considered contaminated (potentially infectious).* During normal testing, any meter may come in contact with blood. Lancing devices may also be considered sharps. Disposal of sharps is regulated by law in many jurisdictions.* on page 17.

3 Putting the Meter into Operation

Before using the meter for the first time, perform the following steps:

1 Insert batteries and/or connect the power adapter

2 Set the current date and time

3 Enter the settings of choice (language, unit of measure, user administration if applicable, etc.)

Instead of batteries, you can use a special rechargeable battery pack. If you choose this option, order the pack separately from Roche Diagnostics. To recharge, connect the power adapter to the CoaguChek XS Plus meter or to the optional Handheld Base Unit (HBU) and dock the meter.

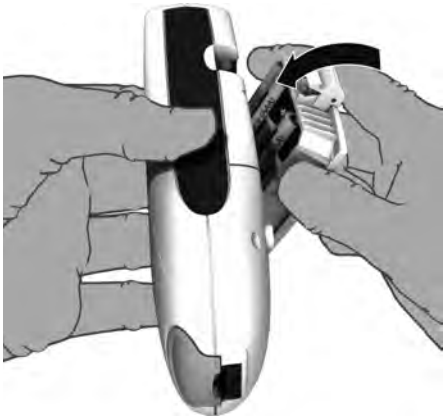
The meter's battery power level indicator is designed for use with either standard, non-rechargeable AA batteries or the dedicated Roche handheld battery pack. We do not recommend the use of off-the-shelf rechargeable batteries in AA format. These have lower voltages than standard AA batteries or the special Roche handheld battery pack. This can lead to incorrect battery power level indications on the meter.

Inserting the batteries

1 With the meter powered off, press the battery compartment cover release tab and slide the cover off.

2 Insert the four batteries in the battery compartment as indicated.

The batteries should last about 80 tests, depending on the type of battery used.



3 Slide the battery compartment back onto the meter and close it.

The meter powers itself on after the batteries have been inserted.

Powering the meter on and off

1 Place the meter on a level, vibration-free surface, or hold it in your hand so it is roughly horizontal.

2 Power the meter on by pressing the ⏻ button for approximately 1 second.

You can also power on the meter directly by inserting a test strip or connecting the power adapter.

3 To power the meter off after use, press the ⏻ button for approximately 1 second.

Checking the software version

After displaying the Roche logo, the meter briefly displays the *Init* (for “initialization”) screen. Here you can check which software version is currently running on your meter. (The Init screen shown here is for illustration purposes only. Version numbers on your meter may differ.)

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4 Meter Setup

Note on presentation of screen elements in this manual

Buttons are screen prompts that cause something to happen when touched. The names of all buttons are either shown as **bold** text or as the icon used on the button (e.g., ✓ for **OK**).

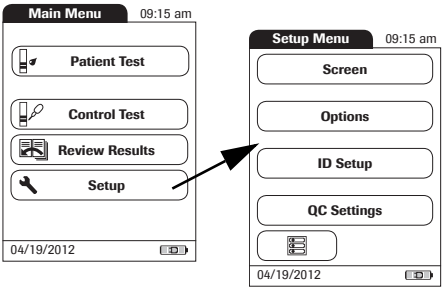
Other screen elements (e.g., Menu titles) are written in *italics*. These screen elements are not active.

If you have **not** set the date and time (after powering on for the first time or because the batteries were removed from the meter for more than 10 minutes), you cannot perform a test. In that case powering on the meter takes you immediately to the *Setup* mode, where you must set the date and time (see page 41 and following).

After date and time have been set, the meter automatically moves to the *Main Menu*, where you can start a test or enter more settings.

You can open any displayed function by touching (or tapping) the button for it with your finger (or a special pen for this purpose). “Tap” means: Touch the button, then remove your finger from the touchscreen. The next screen appears once you remove your finger.

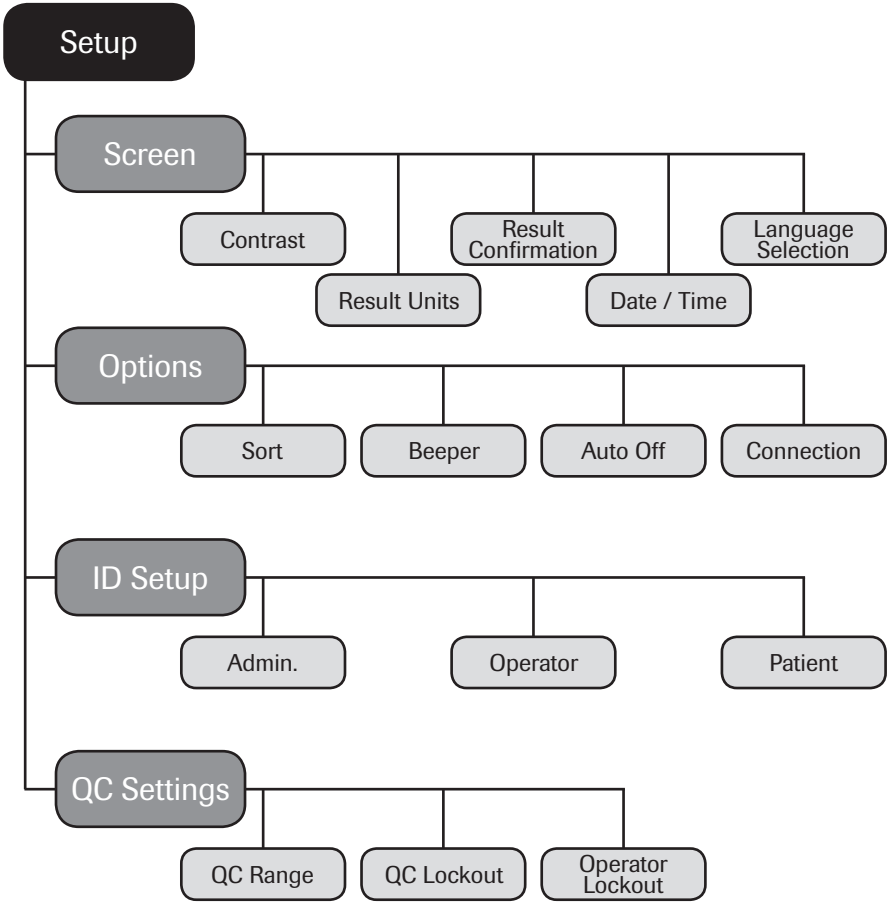
If the meter did not automatically enter the *Setup* mode (e.g., after the batteries were replaced), you can open the *Setup* menu from the *Main Menu*.



1. Touch **Setup** to open the meter settings.
2. Select the group of settings of choice (see the Settings summary following this section.).

Settings summary

The diagram below shows all of the setup areas that can be accessed on the meter.



Group	Subgroup	Setting	Values *
Screen	Contrast		0 – 10 (5 *)
	Result Units		INR *
			INR/SEC
			INR/%Q
	Result Confirmation		Enable
			Disable *
	Language Selection		Dansk
			Deutsch
			English *
			Español
			Français
			Italiano
			Nederlands
			Norsk
			Português
			Suomi
			Svenska
	Date/Time	Date	01/01/2012 *
		Time	12:00 am *
		Date formats	DD.MM.YYYY (01.01.2012)
			MM/DD/YYYY (01/01/2012) *
			YYYY-MM-DD (2012-01-01)
		Time formats	24-hour time format (24h)
			12-hour time format (12h), with am/pm *

* Default settings are labeled with an asterisk (*).

Group	Subgroup	Setting	Values *
Options	Sort		Date/Time *
			Patient ID
			Patient Name
	Beeper	Beeper	Off
			Low
			Medium *
			High
		Key Click	Off *
			On
	Auto Off	[minutes]	Off
			1 … (5*) … 10
			15
			20
			25
			30
			40
			50
			60
	Connection		Off *
			Computer

* Default settings are labeled with an asterisk (*).

Group	Subgroup	Setting	Values *
ID Setup	Admin. (Administrator)		Blank (Off) *
	Operator (Operator List is optional)		Active
			Inactive *
	Patient		No *
			Optional
			Required
QC Settings	QC Range	Default Range*	
		Custom Range	Display Target Value On/Off *
			Deviation from Target Value Percentage (%)
	Operator Lockout (only if the *Operator* option is set to *Active* and an operator list is available)		Off *
			Weekly
			Monthly
			Every 3 months
			Every 6 months
			Yearly
	QC Lockout	New code	Yes
			No *
		General	No *
			Daily
			Weekly
			Monthly

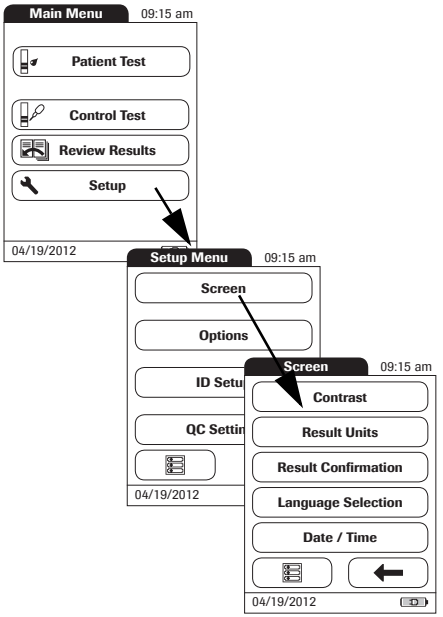
* Default settings are labeled with an asterisk (*).

Screen setup

The *Screen* setup area contains the options for changing the display.

Contrast

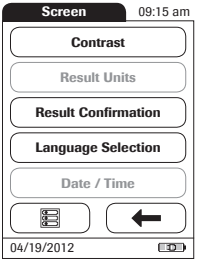
Use the *Contrast* menu to adjust the display to your ambient light conditions and make it easier to read.



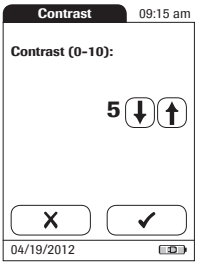
1 From the *Main Menu*, touch **Setup** to open the meter settings.

2 From the *Setup Menu*, touch **Screen**.

3 From the *Screen* menu, touch **Contrast**.



If a button is grayed out, this means the function is not available.



4 Touch ↑ or ↓ to change the contrast in a range from 0 to 10.

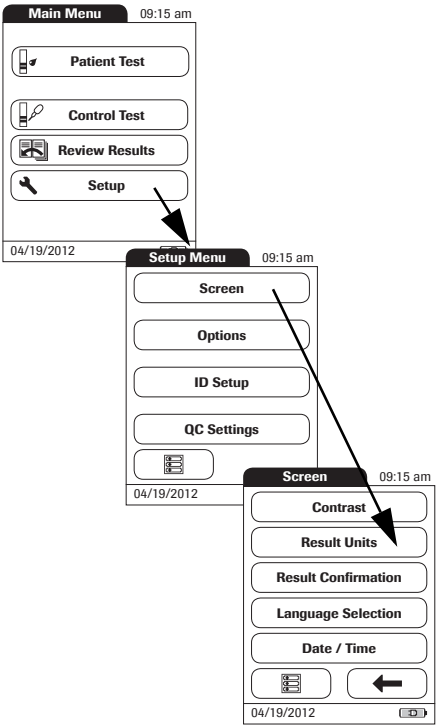
- Contrast “0” makes the display very dark.
- Contrast “10” makes the display very light.

5 Touch ✓ to save this setting, or

touch ✗ to exit this menu without saving any changes.
The display automatically returns to the previous screen.

Result Units

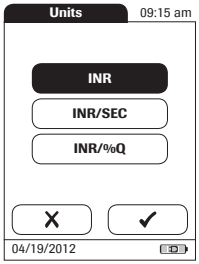
Use this setting to select the unit(s) of measure to be displayed with the results.



1 From the *Main Menu*, touch **Setup** to open the meter settings.

2 From the *Setup Menu*, touch **Screen**.

3 From the *Screen* menu, touch **Result Units**.



The current unit of measure setting is highlighted (white type on a blue background). You can select either:

- INR
- INR and seconds
- INR and Quick value in %

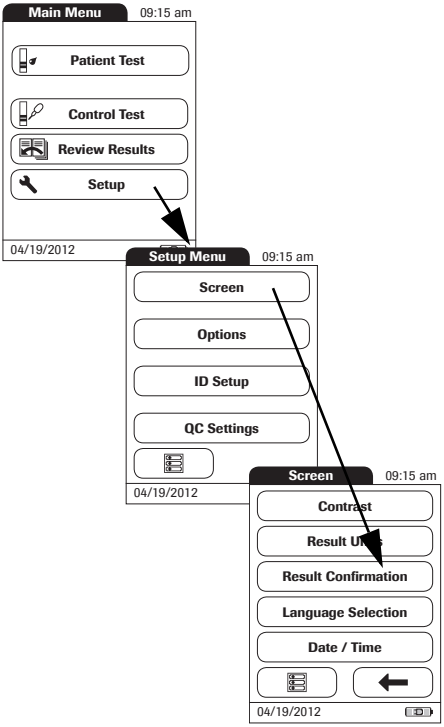
4 Touch the button to select the unit of measure of choice. Your selection is now highlighted.

5 Touch ✓ to save this setting, or

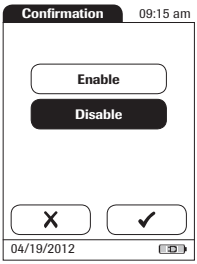
touch ✗ to exit this menu without saving any changes.
The display automatically returns to the previous screen.

Result Confirmation

In some circumstances, it may be useful for operators to confirm the validity of their results. Use this setting to prompt operators to confirm the results of every test.



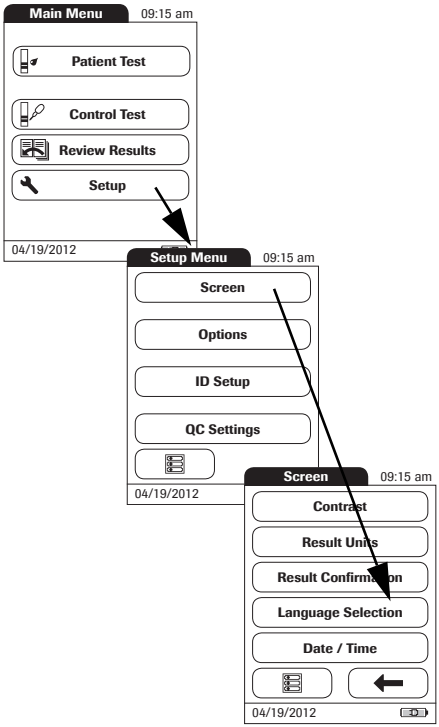
1. From the *Main Menu*, touch **Setup** to open the meter settings.
2. From the *Setup Menu*, touch **Screen**.
3. From the *Screen* menu, touch **Result Confirmation**.



4. Touch **Enable** or **Disable**. Your selection is now highlighted.
5. Touch ✓ to save this setting, or touch ✗ to exit this menu without saving any changes.
   The display automatically returns to the previous screen.

Language Selection

Use this setting to select the language for all displays (that contain text).



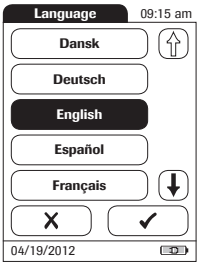
1 From the *Main Menu*, touch **Setup** to open the meter settings.

2 From the *Setup Menu*, touch **Screen**.

3 From the *Screen* menu, touch **Language Selection**.

The current language setting is highlighted (white type on a blue background). You can select either:

- Dansk
- Deutsch
- English
- Español
- Français
- Italiano
- Nederlands
- Norsk
- Português
- Suomi
- Svenska



4 Touch ⇧ or ⇩ to display the language of choice on the screen.

If the arrow is just an outline ⇧ ⇩, you have reached the end of the list in the repective direction.

5 Touch the button to select the language of choice. Your selection is now highlighted.

6 Touch ✓ to save this setting, or

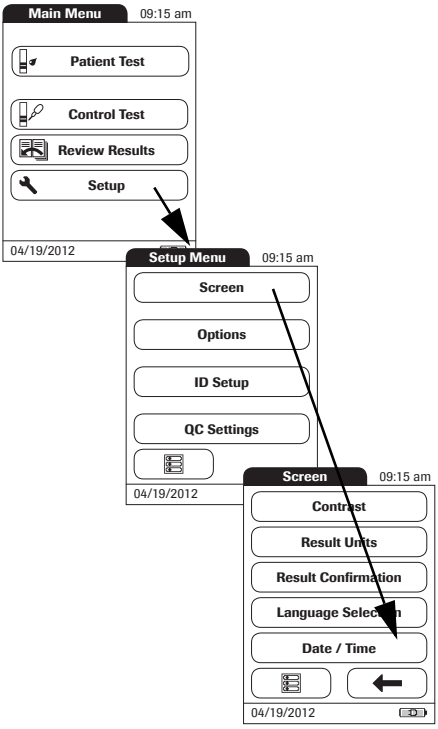
touch ✗ to exit this menu without saving any changes.
The display automatically returns to the previous screen.

Setting the date

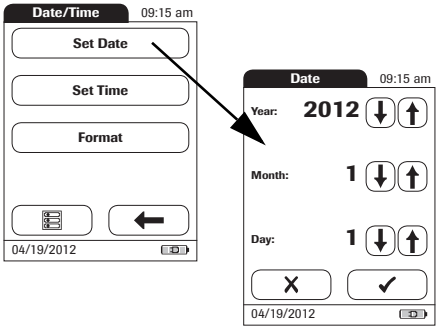
When you power on the meter for the first time (or after a long period without power), the input field for the date automatically appears first. The date (and time) must be entered before the meter can be used further. If at a later time a date adjustment is needed, go to the *Setup* menu, then select the menu of choice.

Both *Date* and *Time* display formats are controlled by the *Format* options you select (see page 45). Options shown in the *Date* and *Time* menus may vary depending on the chosen formats. You can choose between the following display formats:

- Date: Day.Month.Year, e.g., 01.01.2012
- Date: Month/Day/Year, e.g., 01/01/2012
- Date: Year-Month-Day, e.g., 2012-01-01
- Time: 24H or 12H



1. From the *Main Menu*, touch **Setup** to open the meter settings.
2. From the *Setup Menu*, touch **Screen**.
3. From the *Screen* menu, touch **Date/Time**.



4 From the *Date/Time* menu, touch **Set Date**.

5 Touch ⬆ and ⬇ to set the year, then the month, then the day.

6 Touch ✓ to save this setting, or

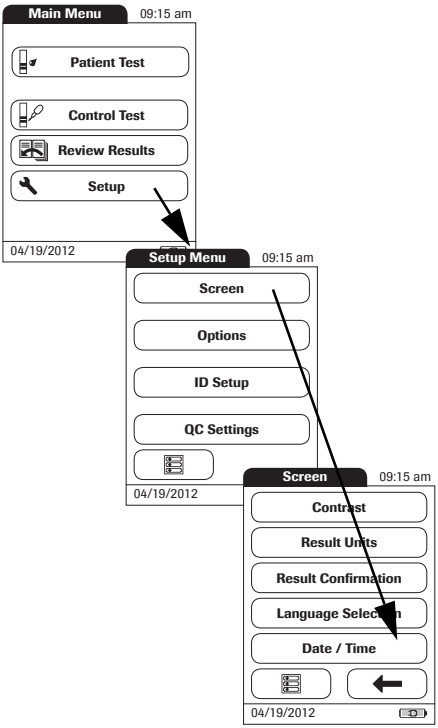
touch ✗ to exit this menu without saving any changes.
The display automatically returns to the previous screen.

If this setup menu appeared automatically after powering the meter on, you must touch ✓ to complete the first date setting.

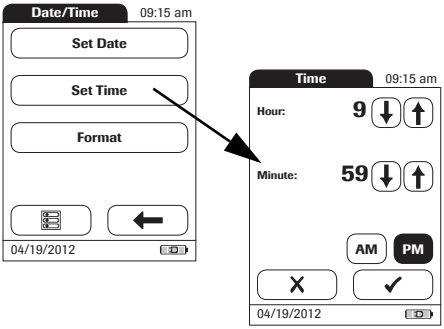
7 Touch ← to return to the *Screen* menu.

Setting the time

When you power on the meter for the first time (or after a long period without power), this *Setup* menu appears automatically after you set the date. If at a later time a time adjustment is needed, go to the *Setup* menu, then select the menu of choice.



1. From the *Main Menu*, touch **Setup** to open the meter settings.
2. From the *Setup Menu*, touch **Screen**.
3. From the *Screen* menu, touch **Date/Time**.



4 From the *Date/Time* menu, touch **Set Time**.

5 Touch ↑ and ↓ to set the hours, then the minutes.

6 Touch ✓ to save this setting, or

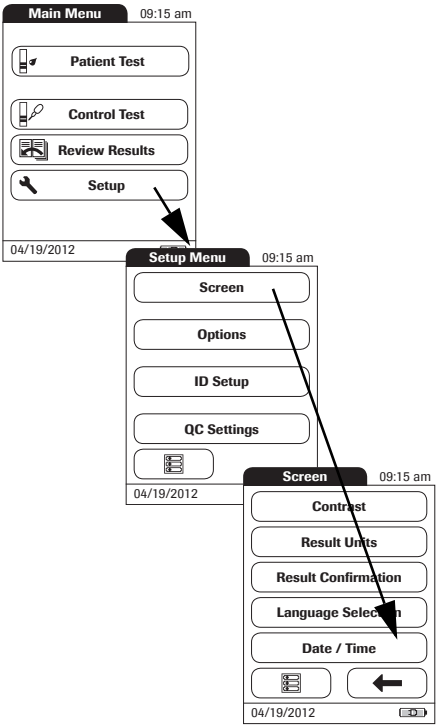
touch ✗ to exit this menu without saving any changes.
The display automatically returns to the previous screen.

If this setup menu appeared automatically after powering the meter on, you must touch ✓ to complete the first time setting.

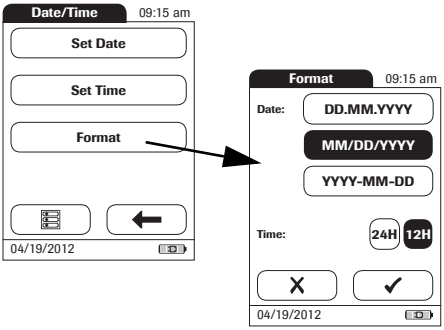
7 Touch ← to return to the *Screen* menu.

Setting the display options for date and time

Select your preferred format for the date and time display.



1. From the *Main Menu*, touch **Setup** to open the meter settings.
2. From the *Setup Menu*, touch **Screen**.
3. From the *Screen* menu, touch **Date/Time**.



4 From the *Date/Time* menu screen, touch **Format**.

The current settings are highlighted. You can select one of the following display formats:

- Date: DD.MM.YYYY (Day.Month.Year), e.g., 30.09.2012
- Date: MM/DD/YYYY (Month/Day/Year), e.g., 09/30/2012
- Date: YYYY-MM-DD (Year-Month-Day), e.g., 2012-09-30
- Time: 24H or 12H

5 Touch the button with the display format of choice for date and time. Your selection is now highlighted.

6 Touch ✓ to save this setting, or

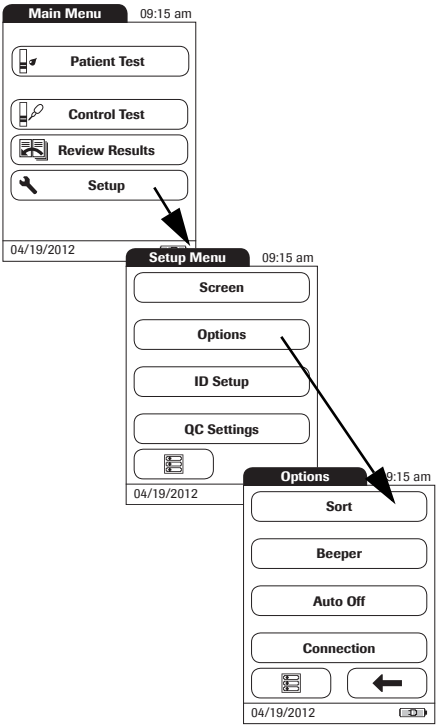
touch ✗ to exit this menu without saving any changes.
The display automatically returns to the previous screen.

7 Touch ← to return to the *Screen* menu.

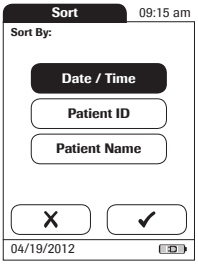
Options setup

Sort

Sort refers to the order in which measured and stored results are displayed when you use the *Review Results* function of the CoaguChek XS Plus meter. You can display stored results chronologically by date and time or by person, based on the *Patient ID*. If you are working with a DMS and a patient list, you can also display the patient list and the stored results sorted by *Patient Name*.



1. From the *Main Menu*, touch **Setup** to open the meter settings.
2. From the *Setup Menu*, touch **Options**.
3. From the *Options* menu, touch **Sort**.



The current setting is highlighted. You may select from the following sort options:

- By **Date/Time**
- By **Patient ID**
- By **Patient Name**

4 Touch the button to select the *Sort by* option of choice. Your selection is now highlighted.

The sort option *Patient Name* is available only when used together with a patient list. Patient lists can only be created with a DMS. For more details see *Data handling*, starting on page 115.

5 Touch ✓ to save this setting, or

touch ✗ to exit this menu without saving any changes.
The display automatically returns to the previous screen.

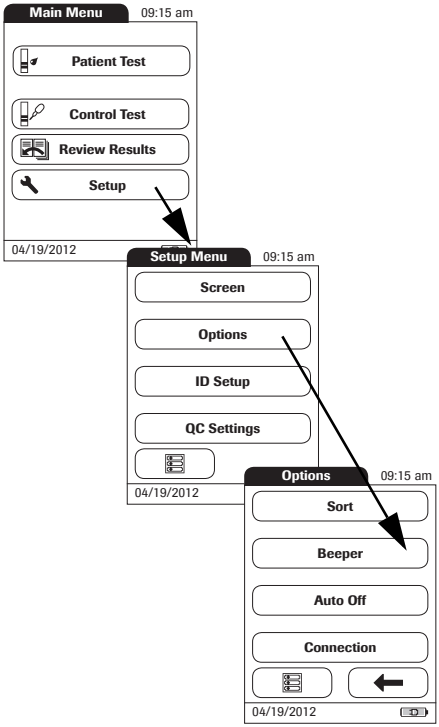
Beeper

The CoaguChek XS Plus meter can display information visually and alert you to special circumstances with a *Beeper*. When the *Beeper* is enabled, the meter beeps when:

- it is switched on
- it detects a test strip
- pre-heating of the test strip is complete and you need to apply a sample
- it detects a sample
- the test is completed and the results are displayed (a long beep)
- an error occurs (three short beeps)
- an external power adapter is connected when the meter is on

We recommend that you keep the *Beeper* enabled at all times.

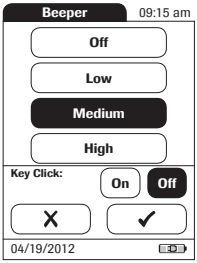
You can also activate a *Key Click*. When a *Key Click* is enabled, the meter clicks briefly every time a button is touched, facilitating the input of information.



1 From the *Main Menu*, touch **Setup** to open the meter settings..

2 From the *Setup Menu*, touch **Options**.

3 From the *Options* menu, touch **Beeper**.



The current setting is highlighted. You may select from the following options:

For the *Beeper*

- **Off**
- **Low**
- **Medium**
- **High**

For the *Key Click*

- **On**
- **Off**

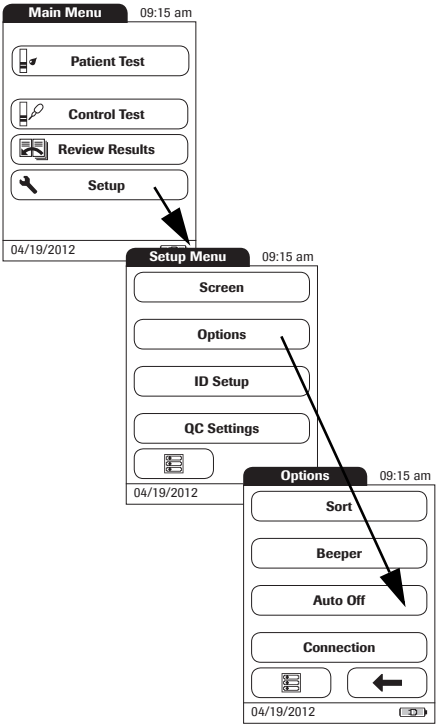
4 Touch the button with the desired setting for the *Beeper*, then touch the button with the setting of choice for the *Key Click*. Both selections are now highlighted.

5 Touch ✓ to save this setting, or

touch ✗ to exit this menu without saving any changes.
The display automatically returns to the previous screen.

Auto Off

You can set up your CoaguChek XS Plus meter so that it powers itself off automatically if it has not been used (no buttons touched or tests run) for a preselected time period. Use this feature to save power and extend the life of the batteries.

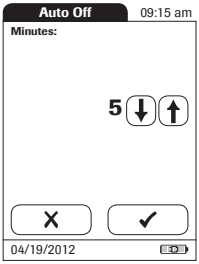


1. From the *Main Menu*, touch **Setup** to open the meter settings.
2. From the *Setup Menu*, touch **Options**.
3. From the *Options* menu, touch **Auto Off**.

If the meter is connected to the power adapter or the Handheld Base Unit, the *Auto Off* function has a different effect:

- **If you work with operator IDs,** the meter switches to *Operator Login*, once *Auto Off* is triggered.
- **If you do not work with operator IDs,** the meter switches to the *Main Menu*, once *Auto Off* is triggered.

For information on *Operator ID*, see *Operator ID* on page 64.



You may select from the following options:

- **Off** (meter never powers itself off)
- Time until meter powers itself off:
  1…10, 15, 20, 25, 30, 40, 50, 60 minutes

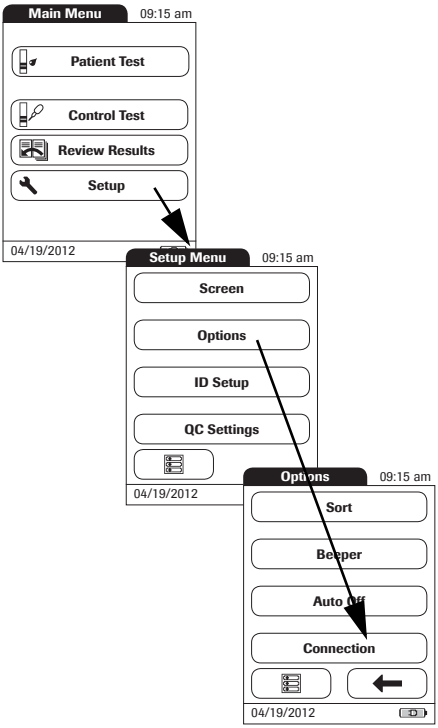
4 Touch ↑ or ↓ to select the time of choice in minutes or to switch the feature off.

5 Touch ✓ to save this setting, or

touch ✗ to exit this menu without saving any changes.
The display automatically returns to the previous screen.

Connection

In the *Connection* menu you can configure the data exchange with external devices. The meter can be connected to a computer.



1. From the *Main Menu*, touch **Setup** to open the meter settings.
2. From the *Setup Menu*, touch **Options**.
3. From the *Options* menu, touch **Connection**.

Computer

The CoaguChek XS Plus meter can connect with a computer or host system running appropriate software (that is, a DMS must be installed). To use this connectivity feature, however, you need the optional Handheld Base Unit. The connection is established in two steps.

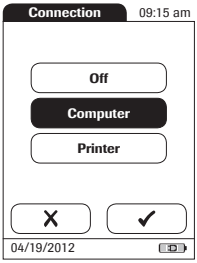
- The meter connects to the Handheld Base Unit via infrared.
- The Handheld Base Unit is either connected to a single computer (via USB) or to a network/host system (via ethernet).

The option *Computer* (when activated) can be used together with a DMS to set up:

- operator lists, or
- patient lists (lists of patients to be tested)

This eliminates the need for manual entry of these data.

In addition, you can transfer test results stored in the meter to other systems for archiving or further evaluation. The option *Computer* controls the meter's ability to communicate with a computer or a network.



4 Touch **Computer**. Your selection is now highlighted.

5 Touch ✓ to save this setting, or

touch ✗ to exit this menu without saving any changes.
The display automatically returns to the previous screen.

Extended data handling functionality is dependent on the capabilities of the particular Data Management System (DMS) being used and may vary. For more information on DMS, please contact your Roche representative.

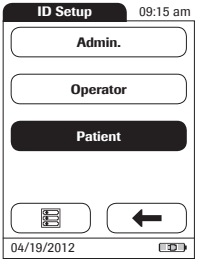
ID setup

Use the *ID Setup* menu to enter settings for user management and patient management. These settings are optional and set to *Off/Inactive* by default; the meter can be operated without these settings.

There are three types of identification used with the meter:

- **System Administrator:** The *Admin.* (Administrator) has special rights to enter certain meter settings and is the only one who can enter and change these settings. It is not necessary for *Admin.* identification to be activated to use the CoaguChek XS Plus meter. However, it might be desired or necessary, depending on the regulatory environment and the site of use.
- **Operator:** The *Operator ID* is assigned to persons who use the meter to run tests. If you want to use *Operator IDs*, you have several options:
  - You may use *Operator IDs* to restrict the use of the meter to qualified personnel or a predefined group of users. In this case an operator list created externally must be transferred to the meter, enabling you to select an *Operator ID* when logging in. For more details see *Data handling*, starting on page 115.
  - You may use *Operator IDs* for informational purposes only, in order to assign stored measurement results to the users who performed the test. In this case *Operator IDs* may be entered directly on the meter (by keypad).
- **Patient:** The *Patient ID* is assigned to the person, whose test results are recorded. You can either:
  - block input of a unique *Patient ID* (in this case, every test is simply numbered in consecutive order)
  - allow a unique *Patient ID* as optional, or
  - require a unique *Patient ID* for every test. Patient lists created externally can also be transferred to the meter, enabling you to select *Patient ID*s for a test from these lists. For more details see *Data handling*, starting on page 115.

Operator IDs can be selected from a list (if available) or entered by using the onscreen keypad. If passwords were created, they **must** be entered via the onscreen keypad. *Patient IDs* can be selected from a list (if available) or entered by using the onscreen keypad.



The buttons in the *ID Setup* menu show what the current settings are (this is just an example, the screen may look different on your meter):

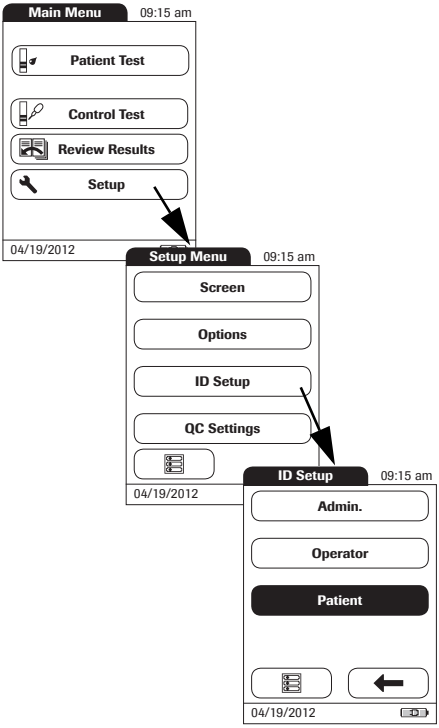
- The standard display of the **Admin.** button means the function is available but not activated (a password for the system administrator/supervisor has not been assigned).
- The standard display of the **Operator** button means the *Operator* login is available but not activated.
- When the **Patient** button is highlighted (that is, when it has a blue background) this means the function is available and activated (either as *Optional* or *Required*).

System Administrator (Admin.)

In the default setting, the meter is not protected with an *Admin.* password, and all setup options are accessible to every user. If you set up an *Admin.* password, the following setup areas are automatically reserved only for the system administrator/supervisor (i.e., the person who knows the password).

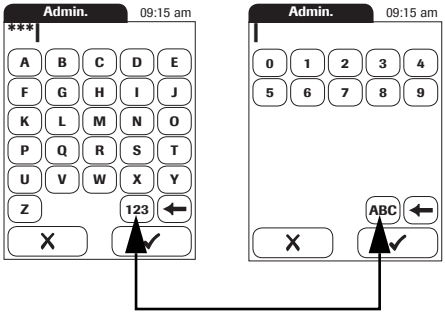
- *Screen: Result Units, Date/Time*
- *Options: Connection* (to a computer)
- *ID Setup* (the entire area)
- *QC Lockout*
- *QC Range*
- *Operator Lockout* (only available in combination with a data management system)

When you enter an *Admin.* password, this password will have to be entered from this point forward before any of the settings above can be changed. The *Admin.* password must also be entered before you can delete or change the *Admin.* password itself. If you forget the *Admin.* password, contact your Roche representative.



If an *Admin.* password has not been set up yet:

1. From the *Main Menu*, touch **Setup** to open the meter settings.
2. From the *Setup Menu*, touch **ID Setup**.
3. From the *ID Setup* menu , touch **Admin.**



4 Using the keypad displayed on the screen, enter the *Admin.* password of choice. The password can consist of up to 20 characters.

Pay close attention to the buttons you press, because the characters are not displayed on the screen. Asterisks are displayed instead (as if entering a password on a computer).

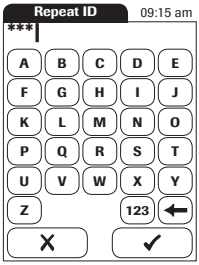
5 Use (123) to switch to input of numbers.

6 Use (ABC) to switch back to input of text.

7 Use (←) to backspace and correct a mistake.

8 Touch ✓ to save this setting, or

touch ✗ to exit this menu without saving any changes.
The display automatically returns to the previous screen.

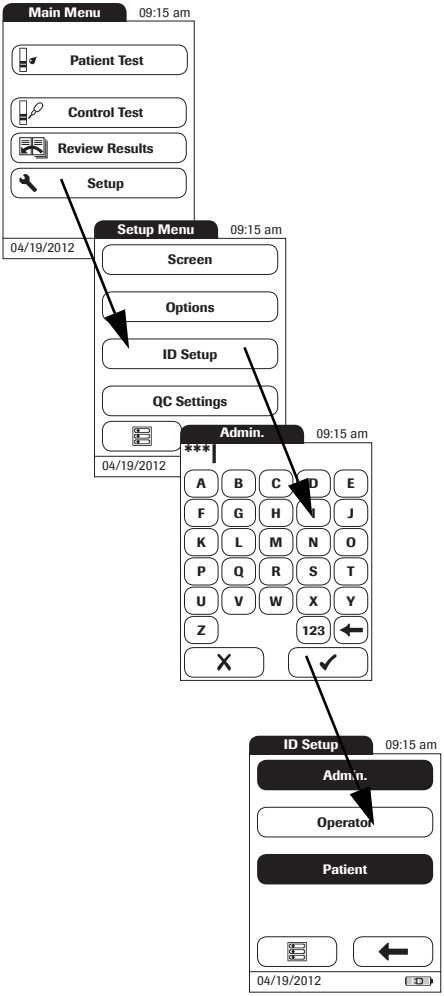


9 Enter the *Admin.* password again (the keypad is automatically displayed again on the screen) to confirm the first entry.

10 Touch ✓ to save this entry, (the *Admin.* password is now set), or

Touch ✗ to exit this menu, the *Admin.* password is not set and is therefore still inactive.

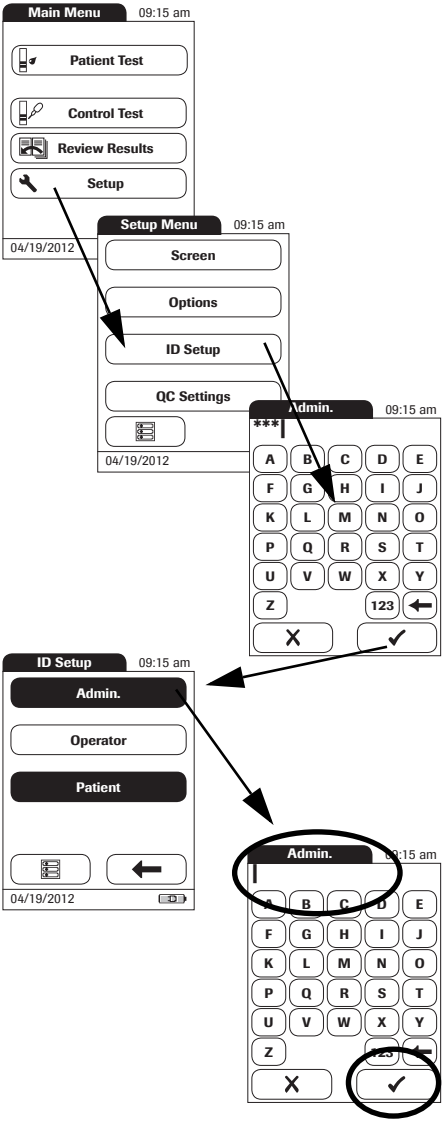
The display automatically returns to the *ID Setup* menu. After you exit the *Setup* menu, only an authenticated administrator may further edit the setup areas as listed before (see page 58).



Changing an existing *Admin.* password:

1. From the *Main Menu*, touch **Setup** to open the meter settings.
2. From the *Setup Menu*, touch **ID Setup**.
3. Using the keypad displayed on the screen, enter the valid *Admin.* password.

   The *ID Setup* menu is displayed. The **Admin.** button is highlighted, which means an *Admin.* password is active.
4. Touch **Admin.**
5. Using the keypad displayed on the screen, enter (and confirm) the new *Admin.* password of choice.



Deactivating an existing *Admin.* password:

1. From the *Main Menu*, touch **Setup** to open the meter settings.
2. From the *Setup Menu*, touch **ID Setup**.
3. Using the keypad displayed on the screen, enter the valid *Admin.* password.

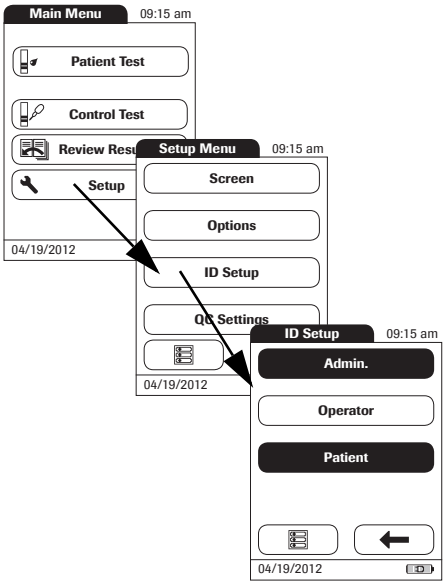
   The *ID Setup* menu is displayed. The **Admin.** button is highlighted, which means an *Admin.* password is active.
4. Touch **Admin.**
5. Immediately touch ✓ to close the keypad on the screen **without** entering a password.

   The *Admin.* password has been deleted and therefore deactivated. The **Admin.** button is no longer highlighted.

Operator ID

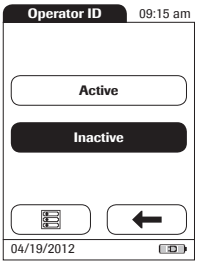
If you want to create a list of *Operator IDs* from which you can select an operator, additional software (a data management system) and the Handheld Base Unit are required (for more details see *Data handling*, starting on page 115).

In the default setting, the *Operator* login is not activated. You can either activate or deactivate *Operator* login on the meter. If activated, an *Operator* has to log in before the *Main Menu* will be displayed and measurements can be performed.



To activate *Operator* login:

1. From the *Main Menu*, touch **Setup** to open the meter settings.
2. From the *Setup Menu*, touch **ID Setup**.
3. From the *ID Setup* menu, touch **Operator**.

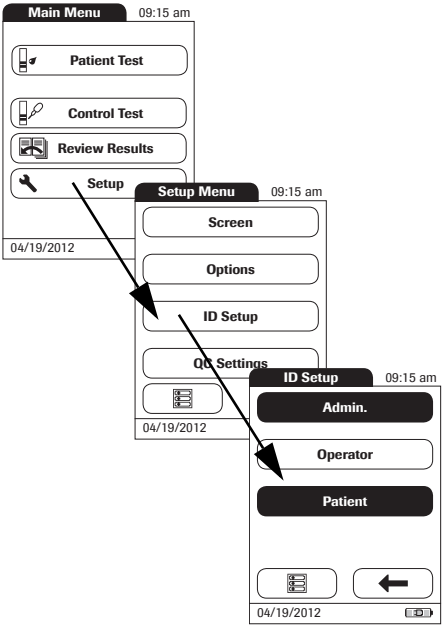


4. Touch the button with the setting of choice for setting up the *Operator* login. Your selection is now highlighted.
5. Touch ✓ to save this setting, or touch ✗ to exit this menu without saving any changes.
   The display automatically returns to the previous screen.

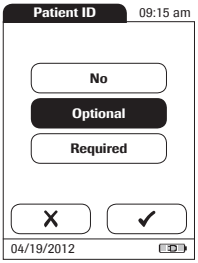
Patient ID

If you want to create a list of *Patient IDs* from which you can select a patient for testing, additional software (a data management system) and the Handheld Base Unit are required (see page 115).

In the default setting, input of *Patient* IDs is set to *No*. This means each test is simply assigned a consecutive number. However, you can require that a *Patient ID* be entered or make it optional.



1. From the *Main Menu*, touch **Setup** to open the meter settings.
2. From the *Setup Menu*, touch **ID Setup**.
3. From the *ID Setup* menu, touch **Patient**.



You may select from the following options:

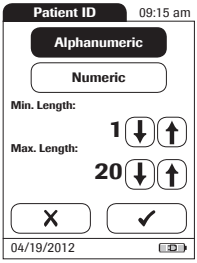
- **No** (tests will be assigned numbers automatically)
- **Optional** (automatic numbering or list/manual input)
- **Required** (list/manual input)

4 Touch the button with the setting of choice. Your selection is now highlighted.

5 Touch ✓ to save this setting, or

touch ✗ to exit this menu without saving any changes.

The settings for the option *No* are now completed. For the options *Optional* and *Required*, continue by selecting the input format.



6 Select the form for input of the *Patient ID*.

You may select from the following options:

- **Alphanumeric**
  Enter any combination of letters and numbers, e.g., “J. DOE 3378”
- **Numeric**
  Enter numbers only, e.g., “3387”
- **Min. Length**
  Enter the minimum number of characters (1 … 20) the *Patient ID* must have.
- **Max. Length**
  Enter the maximum number of characters (1 … 20) the *Patient ID* can have.

7 Touch the button with the format of choice for the *Patient ID*. Your selection is now highlighted.

8 Touch ↑ or ↓ to set the number of characters (length) of choice.

9 Touch ✓ to save this setting, or

touch ✗ to exit this menu without saving any changes.
The display automatically returns to the previous screen.

QC Settings setup

The *QC Settings* menu contains options for enforcing the performance of liquid quality controls by the operator at specified intervals. It also provides the option of customizing the QC Range in accordance with applicable local guidelines.

QC Range

There are two options:

- *Default Range:* The meter displays the QC Range provided by Roche in the code chip.
- *Custom Range:* The option *Custom Range* lets the user define their own QC Range within the default range.

Lockouts (QC Lockout and Operator Lockout)

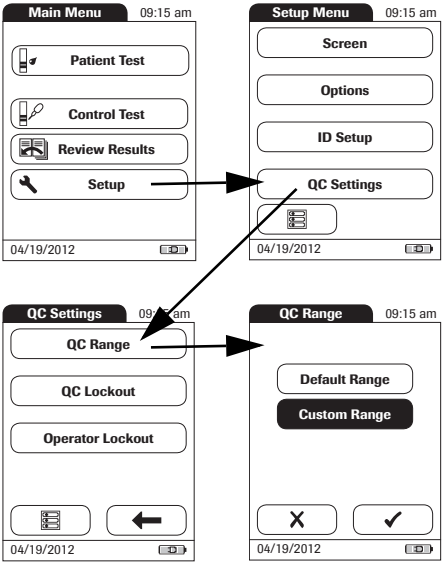
If the liquid quality control test is not performed correctly, or if the result is outside the target value range, the meter is locked from further use. The Lockout can also be set up selectively for individual operators.

A liquid quality control test must be completed successfully before the meter is available again for testing (either by the operator or in general).

The option of setting up an *Operator Lockout* is available **only** when operator lists are created on a data management system (DMS), stored in the meter, and *Operator* login is activated. These lists are only available in connection with a data management system. For more details see *Data handling*, starting on page 115.

QC Range

Liquid Quality control ranges can be customized to comply with local guidelines. The QC Range function enables you to narrow the default range.



1 From the *Main Menu*, touch **Setup** to open the meter settings.

2 From the *Setup Menu*, touch **QC Settings**.

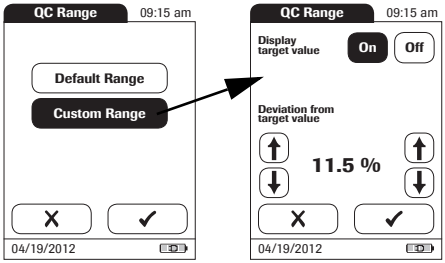
3 From the *QC Settings* menu, touch **QC Range**.

You may select from the following options:

- **Default Range** (Range provided in the code chip is selected and displayed. No target value is displayed.)
- **Custom Range** (The allowed percentage deviation from target value can now be customized. Additionally, you can choose between displaying the target value along with a control test result or not displaying the target value with the control test result.)

4 Touch the button with the setting of choice. Your selection is now highlighted.

- If you selected **Default Range**, touch ✓ to save this setting, or touch ✗ to exit this menu without saving any changes.
- If you selected **Custom Range**, touch ✓ to proceed with corresponding settings, or touch ✗ to exit this menu without saving any changes.
  The display automatically returns to the previous screen.



If you selected **Custom Range**, the *QC Range* screen opens and offers you the following options:

- Display target value (On/Off)
- Deviation from target value (percentage value). See page 69.

For the control solutions, the target value always comes from the information stored in the code chip. If you have chosen **Custom Range**, you can now select an allowed deviation from target value in the range of 0 to 22.5% (in the illustration, 11.5%).

Note: Percentage deviation from target value is always defined using INR values. **Even if you have activated % Quick in the setup, the meter always calculates the deviation using INR values**; this range is then converted to % Quick in a second step. As there is no linear correlation between values expressed as INR and values expressed as % Quick, if you calculate the percentage deviation (11.5 % in the example) using the % Quick target value, your result may deviate from the result calculated by the meter using the INR target value.

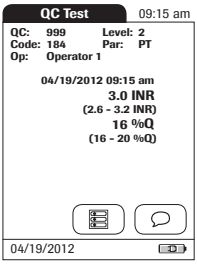
5 Touch **On** (the target value will be displayed with a test result) or **Off** (the target value will not be displayed). Your selection is now highlighted.

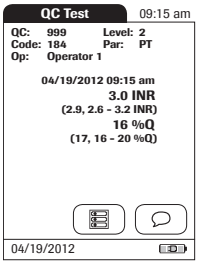
6 Use the arrows to to set the allowed percentage deviation from the target value.

Use the arrows on the left to adjust the whole number before the decimal point. Use the arrows on the right to adjust the number after the decimal point.

7 Touch ✓ to save this setting, or

touch ✗ to exit this menu without saving any changes.
The display automatically returns to the *QC Settings* screen.





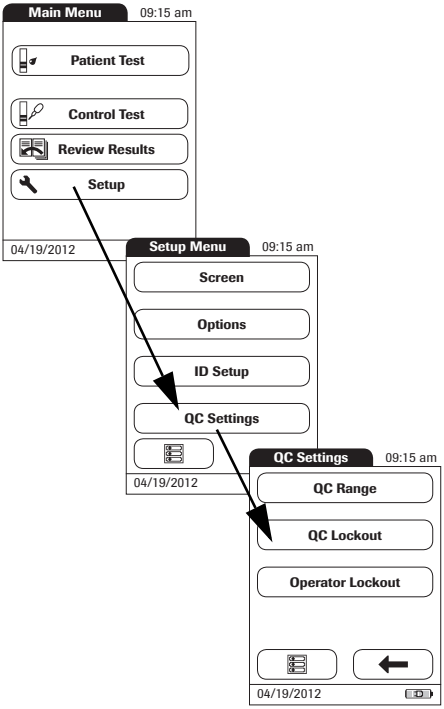
The *Custom Range* and *Target Value* (if set to *On*) appear in a line below the control test result in the QC test and QC memory screens.

In the left hand screen, *Display target value* is set to *Off*: the custom range only is displayed below the control test result.

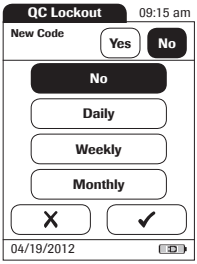
In the right hand screen, *Display target value* is set to *On*: both the custom range and the target value are displayed. The target value (here: 2.9) appears **in front of** the custom range.

QC (quality control) Lockout

The *QC Lockout* ensures that the optional quality control tests are run on a regular basis. This is independent of the operator, however. **This option should be used if you work without operator lists.** It is also possible to mandate *Operator Lockouts* and *QC Lockouts* in parallel. In addition to defining time intervals, *QC Lockout* can also be used to specify that a quality control test must be carried out when a new test strip lot is used (**New Code**).



1. From the *Main Menu*, touch **Setup** to open the meter settings.
2. From the *Setup Menu*, touch **QC Settings**.
3. From the *QC Settings* menu, touch **QC Lockout**.



4 Select the triggers, based on lot and/or time, for requiring a quality control test.

You may select from the following options:

- **New Code Yes/No** (applies every time a new test strip lot is used)

The general intervals are:

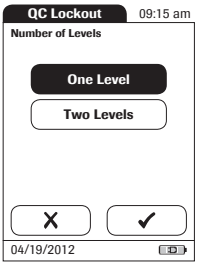
- **No**
- **Daily**
- **Weekly**
- **Monthly**

5 Touch the button with the option of choice when changing the test strip lot.

6 Touch the button to select the interval of choice. Your selection is now highlighted.

7 Touch ✓ to save this setting, or

touch ✗ to exit this menu without saving any changes.



8 For every option except for **No**, you must now indicate the number of levels in which the quality control must be performed.

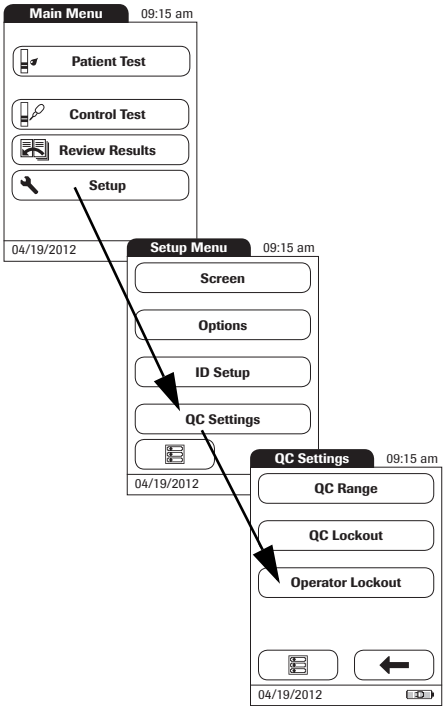
9 Touch ✓ to save this setting, or

touch ✗ to exit this menu without saving any changes.
The display automatically returns to the previous screen.

Operator Lockout

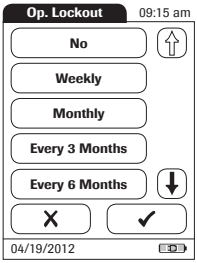
Optional liquid quality controls can be used to ensure that an operator is performing tests properly on the CoaguChek XS Plus meter.

The *Operator Lockout* function constrains an operator, who has been set up in the list, to perform these quality controls on a regular basis.



1. From the *Main Menu*, touch **Setup** to open the meter settings.
2. From the *Setup Menu*, touch **QC Settings**.
3. From the *QC Settings* menu, touch **Operator Lockout**.
   If this button is disabled (grayed out), either no operators have been set up or the *Operator ID* option has been deactivated.

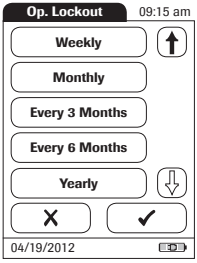
The option of setting up an *Operator Lockout* is available only when operator lists are created on the DMS. For more details see *Data handling*, starting on page 115. If you are not working with a DMS, only the *QC Lockout* is available (see *QC (quality control) Lockout* on page 72).



4 Select the interval of choice in which the mandatory quality control tests must be performed.

You may select from the following options:

- **No** (deactivated)
- **Weekly**
- **Monthly**
- **Every 3 Months** or **Every 6 Months**
- **Yearly**

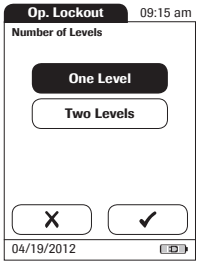


5 Touch ↑ and ↓ to display the option of choice on the screen.

6 Touch the button to select the interval of choice. Your selection is now highlighted.

7 Touch ✓ to save this setting, or

touch ✗ to exit this menu without saving any changes.



8 For every option except for **No**, you must now indicate the number of levels in which the quality control must be performed.

9 Touch ✓ to save this setting, or

touch ✗ to exit this menu without saving any changes.
The display automatically returns to the previous screen.

5 Testing a Blood Sample

What you need:

- CoaguChek XS Plus meter
- CoaguChek XS PT Test Strips and matching code chip
- When testing with capillary blood:
  - Single-use lancing device approved for professional use (e.g., the Accu-Chek Safe-T-Pro Plus lancing device or the CoaguChek Lancets)
  - CoaguChek Capillary Tubes/Bulbs (optional)

  Do not use glass capillary tubes or capillary tubes that contain anticoagulants.
- Cotton ball and alcohol wipe

Important notes

Always …

- … close the strip container immediately after removing a test strip.
- … operate the meter at an ambient temperature between 15 °C and 32 °C (59 °F and 90 °F).
- … place the meter on a level, stable surface (table) or hold it so it is roughly horizontal.
- … follow the information on correct handling of test strips in the package insert.
- … keep the test strip guide and housing clean. See also the chapter entitled *Cleaning and Disinfecting the Meter* (starting on page 119).

Protection against infection:
When collecting samples always observe the general precautions and guidelines relating to blood sampling (see page 16).

Dispose of all test strips used for patient testing in accordance with the disposal policy of your laboratory or practice (see page 16)

Never …

- … store the meter at extreme temperatures (greater than 40 °C or 104 °F) while it is in regular use.
- … store the meter in damp or humid conditions without protection.
- … remove or insert the code chip while the meter is performing a test.
- … use the code chip from a pack of strips other than the one in use.
- … touch or remove the test strip during a test.
- … wait more than 15 seconds after a fingerstick before applying the blood.
- … fingerstick a patient with wet hands (residues of water, sweat, or alcohol).
- … add more blood after the test has begun.
- … perform a test with a drop of blood from a previous puncture.

CAUTION

Accuracy/precision of measured results:
Failure to comply with the above may lead to inaccurate results. An incorrect result may lead to an error in diagnosis, therefore posing danger to the patient.

Getting a good capillary blood sample

To get a suitable drop of blood:

- Warm the hand. Have the patient hold it under his or her arm or use a hand warmer. Wash hands with soap and warm water. Dry thoroughly.
- Have the patient let that arm hang down by his or her side before lancing a finger.
- Massage the finger from its base.

Use these techniques until the fingertip has increased color.

- Immediately after lancing, massage gently along the side of the finger to obtain a good blood drop without pressing or squeezing too hard.
- Apply the blood drop to the test strip immediately (**within 15 seconds**).
- Optionally, you may use a CoaguChek Capillary tube/bulb to collect the fingerstick blood sample.

CAUTION

When washing or disinfecting the patient's finger, allow it to dry thoroughly. Residues of water or disinfectant on the skin can dilute the drop of blood and so produce false results.

Getting a good result from venous whole blood

For sample collection use a standard blood collection device. **Do not use anti-coagulants** (e.g., EDTA, citrate, fluoride, oxalate, or heparin) to collect the blood sample. Venous blood samples may be collected from a **venous line**.

If venous samples are collected by **venipuncture**, note the following:

- Use a needle at least 23 G (approx. 0.65 mm) or larger in size.
- Discard the first **four drops** of blood collected (within the first 10 seconds). Then immediately apply one drop of blood (at least 8 µL) directly onto the target area of the test strip. Ensure that no air bubbles are introduced into the sample.

Protection against infection

When collecting samples always observe the general precautions and guidelines relating to blood sampling (see page 16).

Dispose of all test strips used for patient testing in accordance with the disposal policy of your laboratory or practice (see page 16).

Preparing to test

1. Have the test strip container at hand.
2. Make sure that the code chip supplied with these test strips is at hand.

Each pack of test strips contains a code chip. The number on the code chip and the number on the test strip container must match. A capital **S** in front of the number indicates that this code chip is for test strips. (A capital **C** in front of the number indicates that it is a control solution code chip. See Chapter 6, *Control Testing and Quality Control*).

Test strip code chip

The code chip provides the meter with important information that it needs to perform the coagulation test. The chip contains information about the test method, the lot number, and the expiration date. The code chip is required, whenever a new test strip lot is used, so that the meter can read and store the lot information about that particular lot of test strips.

The CoaguChek XS Plus meter stores the data from up to 60 code chips that have been inserted.

- Do not forget to use the test strip code chip that is supplied with each pack of test strips before you perform the first test with these strips. We recommend that you leave the code chip in the meter to protect the electrical contacts in the meter from becoming dirty.
- Each code chip belongs to a particular lot of test strips. Only remove the code chip when you are testing with test strips taken from a new pack.
- Protect the code chip from moisture and equipment that produces magnetic fields.

Inserting the code chip

1 Remove the old code chip, if one is inserted in the meter.

2 Check that the number on the code chip matches the number on the label of the test strip container.

3 Slide the new code chip into the code chip slot (as shown) until you feel it snap into place.

If the code chip is missing or incorrectly inserted, error messages appear in the display (refer to the *Troubleshooting* section of this manual).

Powering on the meter

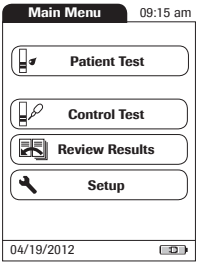
1 Place the meter on a level, vibration-free surface, or hold it in your hand so it is roughly horizontal.

2 Power the meter on by pressing the ⏻ button for approximately 1 second.

You can also power on the meter directly by inserting a test strip or connecting the power adapter.

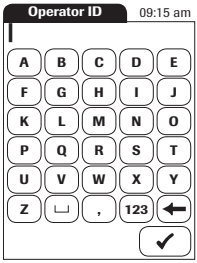
The next steps depend on whether you work with the function *Operator ID* set to inactive or active (see *Data handling* on page 115).

If the function *Operator ID* is inactive:



3 Wait until the *Main Menu* is displayed.

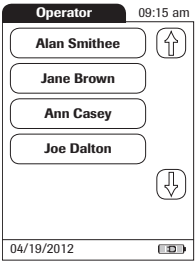
If the function *Operator ID* is active:



Without operator list:

3 You are now prompted to enter an *Operator ID*.

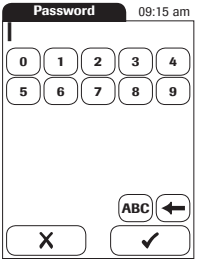
■ Enter the *Operator ID* using the keypad. Touch ✓ to move to the next screen.



With operator list:

3 Wait until the operator list is displayed.

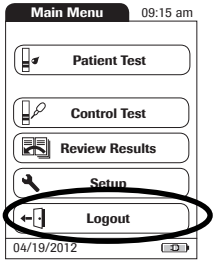
4 Select the operator of choice by touching the corresponding button.



5 Enter the (optional) password.

6 After you enter the password, touch ✓ to log on. The *Main Menu* is displayed and you can start the test.

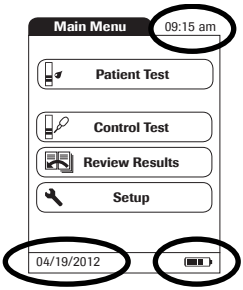
7 When you touch ✗, the operator pick list is displayed again.



When the tests are completed or another operator wants to perform additional tests, touch **Logout** to log out (this button is available only when the *Operator ID* is activated). The meter returns to the display of the operator pick list.

Note: Extended data handling functionality is dependent on the capabilities of the particular Data Management System (DMS) being used and may vary. For more details see *Data handling*, starting on page 115.

Performing a test

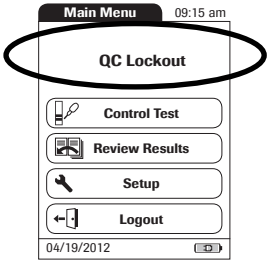


1 Check the battery level.

- If the battery icon turns red (one bar left), there may not be enough power left for another test.
- If there are no bars left in the battery icon, you cannot perform any more tests. Power the meter off using the ⏻ button.

  In both cases, restore power by inserting new batteries, recharging the battery pack, or using the power adapter.

2 Check that the date and time are correct. Correct any wrong entries as described in Chapter 4, *Meter Setup/Setting the date.*

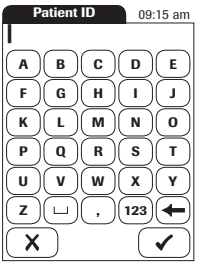


If a lockout (*Operator* or *QC Lockout*) is displayed instead of the **Patient Test** button, you must run a liquid quality control test before you can perform a patient test (refer to Chapter 6, *Control Testing and Quality Control*). When the meter is in lockout status, a test cannot be performed.

The next steps depend on whether you work **with** or **without** patient lists.

Without patient list

3 Touch **Patient Test**.

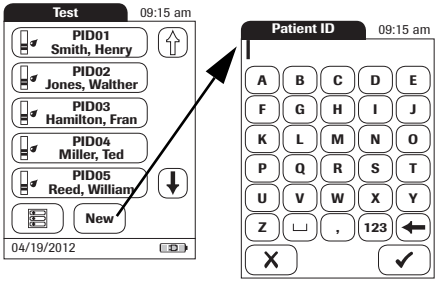


4 If the *Patient ID* option was chosen as either *Optional* or *Required* when the meter was set up (see *Meter Setup/ Patient ID*), you are prompted to enter a *Patient ID*.

- If *Required*, enter the *Patient ID*, then touch ✔ to move to the next screen.
- If *Optional*, ignore the prompt and touch ✔ to move to the next screen. The meter will assign the test a consecutive number.
- If neither option was chosen, a screen appears that prompts you to insert a test strip.
- Continue with Step 8.

With patient list

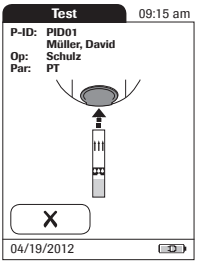
5 Touch **Patient Test**.



6 Touch ⇧ and ⇩ to display the entry of choice. Select the patient to be tested from the list.

7 If the patient is not in the list, touch **New** to create a new entry. You must now enter a *Patient ID*.

Note: Extended data handling functionality is dependent on the capabilities of the particular Data Management System (DMS) being used and may vary. For more details see *Data handling*, starting on page 115.



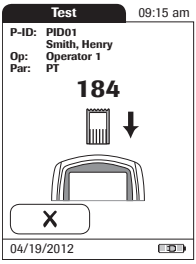
8 The test strip icon prompts you to insert a test strip. Remove a test strip from its container and close the container again with the stopper.

Exposure to external influences (such as humidity) may deteriorate the test strips and may lead to error messages. Therefore, always close the strip container immediately after removing a test strip.

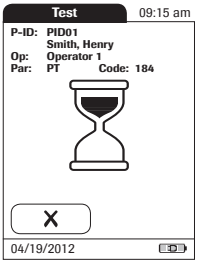
9 Hold the test strip so the lettering with the test name is facing upward.

10 Slide the test strip into the test strip guide in the direction indicated by the arrows.

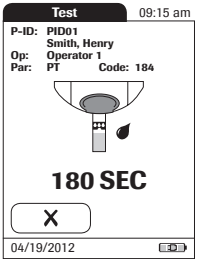
Slide the test strip in as far as it will go. A beep indicates that the meter has detected the test strip (provided the beeper is enabled).



If you use a new test strip lot and have not inserted the code chip yet, you must do so now. Otherwise you cannot perform a test. The meter displays the number of the code chip belonging to the new test strip lot. Depending on the setting, you may also be required to run a liquid quality control test at this point.



The hourglass icon shows that the test strip is warming up. When the warming-up process is complete, a further beep (provided the beeper is enabled) indicates that you can now apply blood.

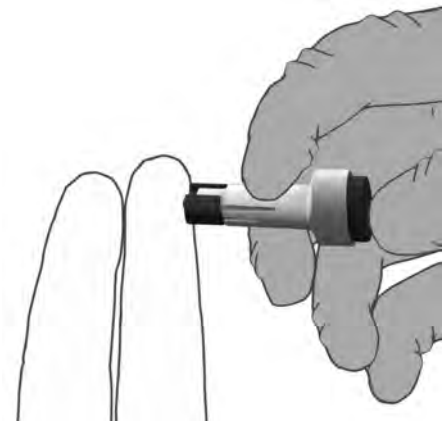


The blood drop icon flashes to indicate that the meter is ready to perform the test and is waiting for blood to be applied.

A 180 second countdown begins. You must apply the drop of blood to the test strip before the countdown ends. Otherwise you will receive an error message.

WARNING

Use only a single-use lancing device that is approved for use by health-care professionals, such as the Accu-Chek Safe-T-Pro or Safe-T-Pro Plus lancing devices, or the CoaguChek Lancets (professional-use lancets available only in the United States). Follow the manufacturer's instructions.

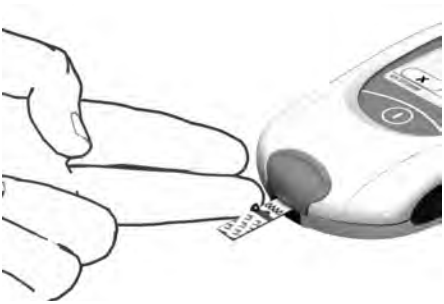


11 Now lance the side of a fingertip with the lancing device.

We recommend obtaining the capillary blood from the side of the fingertip as this causes the least pain.

Massage the lanced finger gently until a drop of blood is formed. Do not press or squeeze the finger.

Apply the **first drop** of blood from the finger.

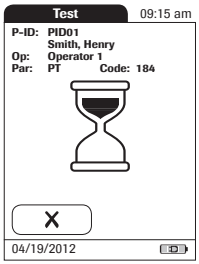


12 Apply the blood (8 µL) directly from the finger to the semicircular, transparent sample application area on top of the test strip.

- … or you can touch the blood drop against the side of the sample application area. The test strip draws up the blood by capillary action.
  During this process you must hold the blood drop to the test strip until the flashing blood drop icon has disappeared and the meter beeps (provided the beeper is enabled).
- … you can also apply the blood using the optional CoaguChek capillary tube.

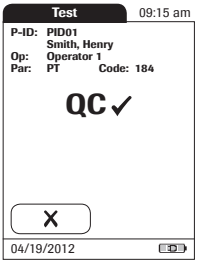
Apply the blood drop to the test strip within **15 seconds** of lancing the fingertip. Applying blood after this period of time may lead to an erroneous result (as the coagulation process would already have started).

When applied from above, the blood must cover the entire sample application area.



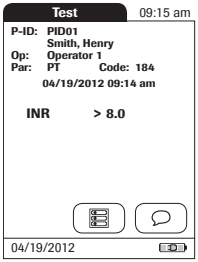
You hear a beep tone when you have applied enough blood (provided the *Beeper* is enabled). The blood drop symbol disappears and the test starts.

Do not add more blood. Do not touch the test strip until the result is displayed. Failure to comply with the above may lead to error messages.



The meter performs an automatic quality control test on the test strip before it displays the test result. “QC” appears in the display.

Following a successful outcome of the quality control test, a checkmark appears after “QC.”



The result is displayed in the unit you chose when setting up the meter. It is automatically saved.

The valid measuring ranges for CoaguChek XS PT test strips are:

- INR: 0.8–8.0
- %Q: 120–5
- Sec: 9.6–96

Results that are above or below the measuring range are indicated by the symbols > (above) or < (below).

If a “c” is displayed along with the result: This may occur if the hematocrit value is very low or due to erroneous blood collection (e.g., wet hands). Repeat the measurement and make sure that the patient's hands are dry. If the message persists, perform a hematocrit check.

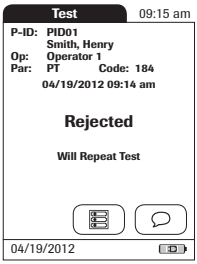
When interpreting results, refer to the detailed information on limitations and interferences included in the limitations section of the test strip package insert.

Accepting or rejecting a test result

If this function is enabled, you may choose to accept or reject a test result. When the result is displayed, touch

- **Reject** or
- **Accept**

If you reject a result, you must enter a comment with an explanation.

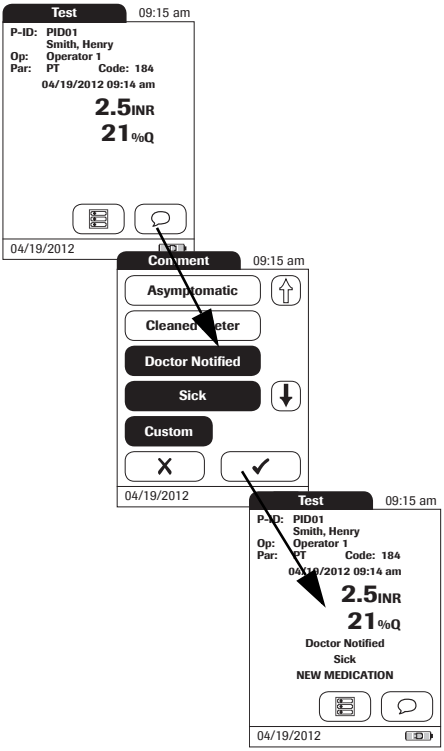


If you reject the result, this test result is no longer displayed. However, the test entry is stored.

Adding comments

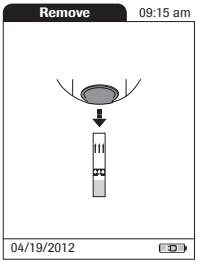
You can add up to three comments to a test result. Comments can provide, for example, additional information about the test conditions or the patient. A comment may be up to 20 characters in length. You can open the function for adding comments directly in the results screen. To add comments:

If you want to add a comment, do not remove the test strip. Once the strip is removed, the meter automatically returns to *Main Menu* and a comment can no longer be added.



1. In the *Test* screen, touch 💬.
2. Select the desired predefined comment(s) from the display list (if configured) or
3. Touch **Custom** to enter your own custom comment. Use the keypad (as with login) to enter your comment.
4. Once you have selected the desired comment(s), touch ✔ to return to the results screen.

Test results are also saved when the meter is powered off in the results screen or automatically powers off.



After the test result is displayed, touch . You will be prompted to remove the strip.

5 Remove the test strip from the meter.

6 Power the meter off.

7 Clean the meter if necessary (see Chapter 9, *Cleaning and Disinfecting the Meter*).

Protection against infection

When collecting samples always observe the general precautions and guidelines relating to blood sampling (see page 16).

Dispose of all test strips used for patient testing in accordance with the disposal policy of your laboratory or practice (see page 16).

6 Control Testing and Quality Control

The CoaguChek XS Plus meter has a number of built-in quality control functions.

- A check of the electronic components and functions every time the meter is powered on.
- A check of the test strip temperature while a test is in progress.
- A check of the expiration date and lot information on the test strip carried out by the code chip.
- A two-level, onboard quality control test and patient result determination within a single test chamber.

Roche offers optional liquid quality controls for the CoaguChek XS Plus system. These controls are provided to assist with regulatory compliance requirements as applicable to your facility.

To perform an optional liquid quality control test using control solutions, you need:

- CoaguChek XS Plus meter
- The test strip code chip supplied with the test strip container you are using. A code chip is provided with every test strip package.
- Test strips that came with the code chip mentioned above
- Bottles of CoaguChek XS Pro PT Controls, diluent droppers, and the quality control code chip provided.

You can choose the frequency of liquid quality control tests in the meter setup. (Refer to the chapter entitled *Meter Setup/QC (quality control) Lockout* starting on page 72). If the control results in the display are in the specified range, this confirms that the liquid control test was performed correctly.

Preparing to run a liquid quality control test

Prepare for a liquid quality control test in the same way you would prepare to perform a test with a capillary blood sample. The only difference is the use of control solution instead of blood.

1. Have the test strip container at hand.
2. If you are using the test strip lot for the first time, make sure that the code chip that came with these test strips is at hand.
3. Make sure the bottle of freeze-dried (lyophilized) control plasma and the dropper for making the control solution are at hand. This bottle should remain refrigerated (not frozen) until use.

4. Make sure that the quality control code chip that came with the control solution is at hand.
5. Open the lid of the bottle and remove the rubber cap.
6. Hold the dropper with the sealed dropper neck pointing upward, then cut off the end of the cap with scissors. Do not hold the dropper close to your face.

To avoid loss of diluent, hold the dropper by the stem; do not squeeze the bulb of the dropper while cutting the tip.

7 Apply gentle pressure to the reservoir to transfer the entire contents of the dropper to the bottle. Make sure that the dropper does not come into contact with the dried control plasma.

8 Close the bottle again.

9 Make sure the dropper is at hand for the next steps in the liquid quality control test.

10 Swirl the bottle using a circular motion to completely dissolve all of the control plasma inside. **Do not shake the bottle or turn it on its side.** Doing so can cause components in the control plasma to stick to the sides of the bottle. Let the bottle sit undisturbed for 1 minute. Please refer to the control solution package insert.

The control solution is now ready to be applied to the test strip.

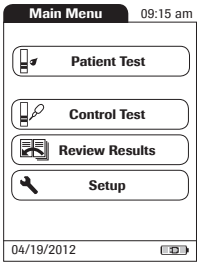
The control solutions may be reconstituted (mixed) after removal from the refrigerator. The resulting solution may be used **up to 30 minutes** after reconstitution.

Performing a liquid quality control test

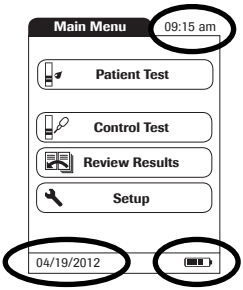
1 Place the meter on a level, vibration-free surface or hold it in your hand so it is roughly horizontal.

2 Power the meter on by pressing the ⏻ button for approximately 1 second.

You can also power on the meter directly by inserting a test strip or connecting the power adapter.



3 Wait until the Main Menu is displayed, or log on as described on page 84.

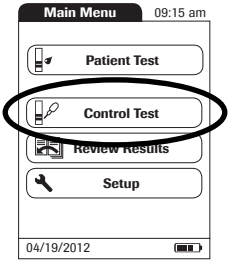


4 Check the battery level.

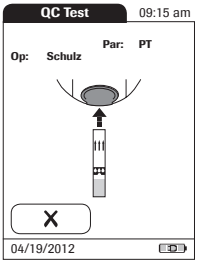
- If the battery icon turns red (one bar left), there may not be enough power left for another test.
- If there are no bars left in the battery icon, you cannot perform any more tests. Power the meter off using the ⏻ button.

  In both cases, restore power by inserting new batteries, recharging the battery pack, or using the power adapter.

5 Check that the date and time are correct. Correct any wrong entries as described in Chapter 4, *Meter Setup/Setting the date.*



6 Touch **Control Test**.



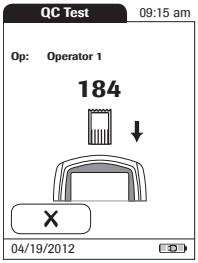
7 The test strip icon prompts you to insert a test strip. Remove a test strip from its container and close the container again with the stopper.

8 Hold the test strip so the lettering with the test name is facing upward.

9 Slide the test strip into the test strip guide in the direction indicated by the arrows.

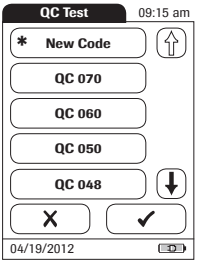
Slide the test strip in as far as it will go. A beep tone indicates that the meter has detected the test strip (provided the beeper is enabled).

Exposure to external influences (such as humidity) may deteriorate the test strips and may lead to error messages. Therefore, always close the container immediately after removing a test strip.



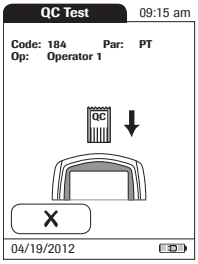
If you are using a new test strip lot and have not inserted the test strip code chip yet, you must do so now. Otherwise you cannot perform a quality control test.

As with the test strips, a quality control code chip is also provided with the control solutions. This chip informs the meter about the acceptable ranges of results for that lot of controls. The information on the code chip is retained in the memory so you can use the same control solutions at any time.



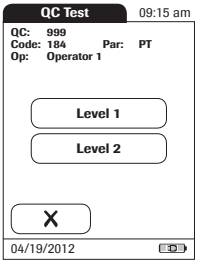
10 Select the code stored for your current control solution, or touch **New Code** to use a new control solution.

The first time you run a control, the meter skips this *QC Test* screen option because there are no code chip parameters in memory yet. The next time you use the control, this screen will display, offering you a pick of the code(s) already stored as well as the option **New Code**.

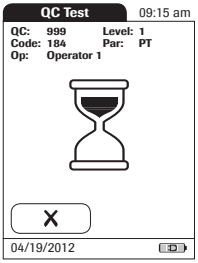


If you are using a new control solution, remove the strip code chip from the meter and insert the code chip that came with the control solution instead.

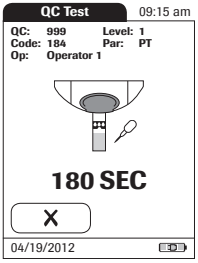
If the code chips get mixed up, check the letter on the code chips to tell them apart: A capital **S** in front of the number indicates that this code chip is for test strips. A capital **C** in front of the number indicates that it is a control solution code chip.



11 If performing more than one level, select the level for this measurement.



The hourglass icon shows that the test strip is warming up. When the warming-up process is complete, a further beep (provided the beeper is enabled) indicates that you can now apply the control solution.

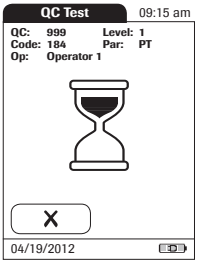


The dropper icon flashes to indicate that the meter is ready to perform the test and is waiting for the sample to be applied.

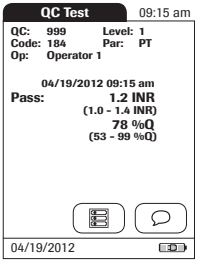
At the same time a 180-second countdown begins. You must apply the sample within this time, otherwise you will receive an error message.

12 Using the dropper, draw up the dissolved contents of the bottle.

13 Apply a single drop of control solution directly from the dropper to the semicircular, transparent sample application area on top of the test strip. Do not add more control solution.

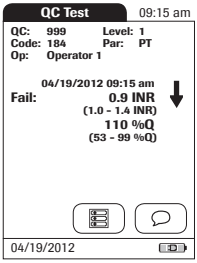


You hear a beep when you have applied enough control solution (provided the beeper is enabled). The dropper icon disappears and the test starts.



The result of the liquid quality control test is displayed. It is automatically saved to memory.

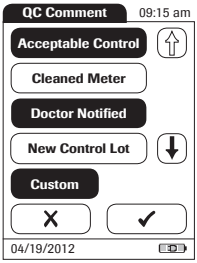
The acceptable range of results for the liquid control is displayed below the current result, along with *Pass* or *Fail*.



If a quality control test fails, an up arrow (too high) or down arrow (too low) is displayed and flashes.

Note: The arrow (next to the result) refers to the INR result only.

If you have selected to display INR and %Quick or INR and seconds, the (up or down) arrow next to the result refers only to the INR value.

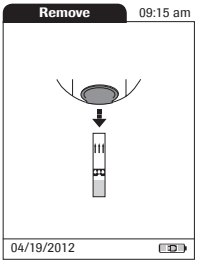


14 If you want to add a comment, touch 💬.

15 Select the desired predefined comment(s) from the pick list (if configured) or

16 Touch **Custom** to enter your own custom comment. Use the keypad (as with login) to enter your comment. A comment may be up to 20 characters in length.

17 Once you have selected the desired comment(s), touch ✔ to return to the results screen.



After the test result is displayed, touch . You will be prompted to remove the strip.

18 Remove the test strip from the meter.

If you are performing a 2-level control, you will now be asked to proceed with the second level.

19 Power the meter off.

20 Remove the quality control code chip from the meter and store it with the controls.

21 Clean the meter if this becomes necessary (see Chapter 9, *Cleaning and Disinfecting the Meter*).

⚠

Dispose of controls and used test strips from control testing in accordance with the disposal policy of your facility. The control solution contains animal material, which should be considered as potentially infectious.

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7 Review Results

The CoaguChek XS Plus meter can save 2000 patient test results as well as 500 liquid quality control tests to memory, together with respective time and date. In addition, up to 60 code chip records (contents of test strip code chips and control solution code chips) are stored. If you are using operator and/or patient lists, a maximum of 5000 *Operator* and 4000 *Patient IDs* is allowed.

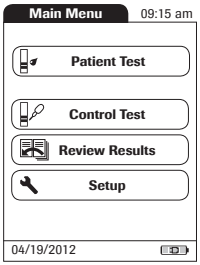
If memory is full when you perform a test, the oldest result is automatically deleted. The most recent result is always saved. This applies both to patient results and to quality control tests. In order to avoid the loss of stored test results, you can archive this data using a data management system and the optional Handheld Base Unit (see page 115).

Viewing test results

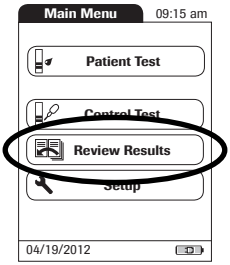
1 Place the meter on a level, vibration-free surface, or hold it in your hand so it is roughly horizontal.

2 Power the meter on by pressing the ⏻ button for approximately 1 second.

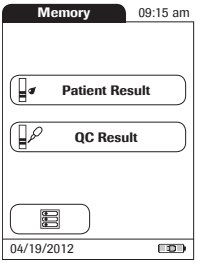
To power the meter off after use, press the ⏻ button for approximately 1 second.



3 Wait until the main menu is displayed.



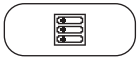
4 Touch **Review Results**.



5 Select the type of results you want to view.

- Display **Patient Result** memory
- Display **QC Result** memory

The following buttons for general use are located in the views described below:



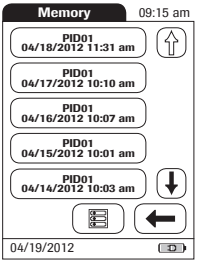
Menu icon: Return to main menu

Return icon: From the single-result display, return to the list of results

Individual icon: List that contains entries for this patient only

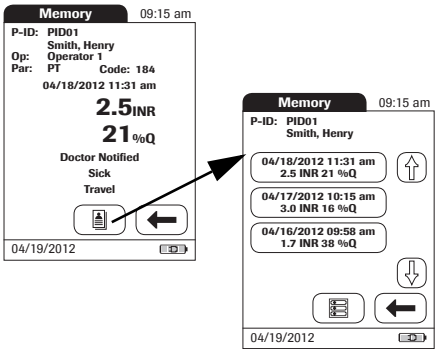
Display patient result memory

This memory area contains all test results for your patients, sorted according to the setting you chose for the option *Sort* (see page 47). If the *Sort* option is set to *Date/Time*, the most recent results are at the top of the list.



1 Touch ⇧ and ⇩ to scroll to the entry of choice on the screen.

2 Touch the entry you want to open.

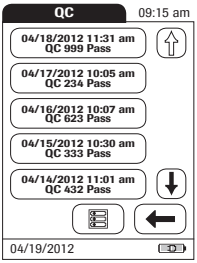


The entry is displayed.

3 Touch 📋 . The results for the selected patient are displayed.

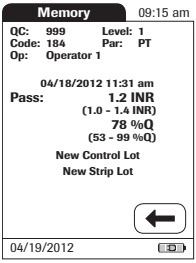
Display QC (quality control) result memory

This memory area contains all liquid quality control tests that were run, sorted chronologically. The most recent results are at the top of the list.



1 Touch ⇧ and ⇩ to scroll to the entry of choice on the screen.

2 Touch the entry you want to open.



The entry is displayed.

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8 Extended Functionalities

Data handling

Note: Extended data handling functionality is dependent on the capabilities of the particular Data Management System (DMS) being used and may vary.

When used in conjunction with the Handheld Base Unit from Roche (available separately), the CoaguChek XS Plus meter can conveniently connect to a data management system (DMS). The main advantages of such a connection between meter and DMS may include:

- Transferring patient lists, operator lists, and settings from the DMS to the meter. In this way the setup for daily work as well as general meter setup can be performed (for one or more meters) quickly and conveniently.
- Transferring all stored test results with the corresponding *Patient ID*, *Operator ID,* and comments from the meter to the DMS. This transfer of data permits further evaluation or proper archiving according to your needs.

Through the DMS the system administrator (such as the POC coordinator) may specify what settings are to be applied to a set of meters within a site or unit (e.g., hospitals or wards). All meters assigned to a specific site and/or unit would consequently share the same settings. The different operator and patient lists (that match a site or unit) are then made available on their respective meters. Other settings such as *QC Lockout* and *Operator Lockout* may easily be set (once) and distributed to all meters.

The option of setting up an *Operator Lockout* is available **only** when operator lists are created on the DMS, stored in the meter, and *Operator* login is activated. For more details on *Operator* login see page 64, for details on *Operator Lockout* see page 74.

Computer (Setup option)

For initial connection to a DMS, the ability to communicate within a network has to be set up as follows:

- In the *Setup* menu, the *Connection* option must be set to *Computer* (see page 54).
- The Handheld Base Unit must be configured correctly. (For details please refer to the manual of the Handheld Base Unit and the Technical Note stored on the Handheld Base Unit itself.)
- Place the meter on a Handheld Base Unit that is connected to the network. The meter will automatically be recognized by the DMS and may now be assigned to a site and/or unit managed by the DMS (if your DMS has that functionality).
- Depending on DMS functionality available, the DMS may transfer settings and lists to the meter as well as enable test results to be transferred from the meter to the DMS.

Operator lists

After powering the meter on, an *Operator* login may be configured. There are two possible configurations for an *Operator* login:

- *Operator* is activated, but there is no list available:
  The *Operator* can log in via the onscreen keypad. The use of the meter is not restricted to a predefined *Operator* group, so *Operator* IDs are entered via the onscreen keypad and stored with test results for informational purposes only.

This first configuration is also available without a DMS.

Meters which are managed by a DMS may receive an *Operator* list.

- *Operator* is activated, a list is available and displayed on the login screen:
  The *Operator* selects the ID from the displayed list. If so configured by the *Administrator*, the *Operator* may also be required to enter a password to log in.

When working with operator lists: The use of the meter is restricted to the operators on this list.

Patient lists

When starting a Patient Test, there will be the option of either selecting a *Patient ID* from a patient list or entering the *Patient ID* using the onscreen keypad. The *Patient ID*, if entered on the DMS, comes with an additional identification entry. Up to 20 characters can be used and assigned as a second confirmation (e.g., name, date of birth).

There are four possible configurations for a *Patient ID* input:

- The *Patient ID* is set to *Optional* or *Required*, and there is no list available:
  A *Patient ID* can be entered manually via the onscreen keypad. The Patient ID is stored with the test result.
- The *Patient ID* is set to *No*, but there is a list available:
  The list of Patient IDs is always shown when starting a test. You may now
  - select a patient from the list;
  - create a new patient entry by touching **New**. Instead of an ID a consecutive number will be assigned to this result.
- The *Patient ID* is set to *Optional* or *Required*, and there is a list available:
  The list of Patient IDs is always shown when starting a measurement. You may now
  - select a patient from the list;
  - create a new patient entry by touching **New**. You may enter a new ID via the onscreen keypad.
- The *Patient ID* is set to “hidden” (only possible with a data management system), and there is a list available:
  A blank list is shown when starting a measurement. You may now create a new patient entry by touching **New** and entering a new ID via the onscreen keypad.

When working with *Patient* lists, you have the following options:

- A *Patient ID* does not have to be on the list to be used.
- The meter displays a warning that the *Patient ID* entered is not on the list.
- The meter displays an error message that the ID was not found on the list of valid *Patient IDs*. You must enter a valid ID to proceed.

Stored test results and comments

When performing a test, the test result will be stored along with additional information, including the *Patient ID*, *Operator ID*, the kind of test performed, and optional *Comments*. The meter comes with a default set of *Comments* that can be assigned to each test result. If you are working with a DMS, these comments can be replaced by the comments in the DMS. The new wording will then be available for selection from the *Comments* list in the meter.

Up to 3 comments can be assigned to each result.

The default preset comments in the meter are:

INR result comments

- Asymptomatic
- Cleaned Meter
- Doctor Notified
- Sick
- Travel
- Lab Draw
- No Action
- Procedure Error
- Under Medication
- Will Repeat Test
- Changed Dosing

QC result comments

- Acceptable Control
- Cleaned Meter
- Doctor Notified
- New Control Lot
- New Lot Number
- New Strip Lot
- New Strip/Kit Lot
- No Action
- Procedure Error
- Proficiency Test
- Repeat Control Test
- RN Notified
- Switched QC Vial
- Will Repeat Test

For more information and technical details, please refer to the manual of the Handheld Base Unit and the Technical Note stored on the Handheld Base Unit itself.

9 Cleaning and Disinfecting the Meter

- Observe the disinfection guidelines of your institution.
- Use gloves.

NOTICE Follow the procedures below to clean/disinfect the meter. Failure to follow these procedures may cause malfunction of the meter.

- Make sure the meter is powered off.
- Do not spray anything onto the meter and do not immerse it in liquid.
- Ensure that cloth or swab/bud is only damp, not wet, to protect against moisture entering the meter.

Recommended cleaning/disinfecting solutions

Use only the following solutions for cleaning/disinfecting the meter (housing and test strip guide).

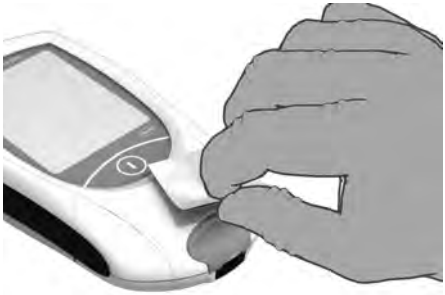
- 70% ethanol or isopropyl alcohol
- 10% sodium hypochlorite solution (1 part bleach to 9 parts de-ionized water, made fresh every 24 hours)

NOTICE Do not use any other disinfectants/cleaning solutions on the meter (housing or test strip guide). Use of other disinfectants/cleaning solutions could result in damage to the meter.

Cleaning/disinfecting the exterior (meter housing)

Use the solutions recommended on page 119 for cleaning/disinfecting the meter exterior. Apply the solutions for a contact time of > 1 minute (refer to the corresponding product labeling).

Ensure that the blue test strip guide cover remains tightly closed while cleaning the meter housing.



1 With the meter powered off, wipe the meter's exterior clean.

Do not let liquid accumulate near any opening. Ensure that no liquid enters the meter.

2 With a fresh dry cloth or lint-free tissue, wipe away residual moisture and fluids after cleaning the housing.

3 Allow wiped areas to **dry for at least 10 minutes** before performing a test.

Cleaning/disinfecting the test strip guide

Use the solutions recommended on page 119 for cleaning/disinfecting the test strip guide. Apply the solutions for a contact time of > 1 minute (refer to the corresponding product labeling) using lint-free cotton swabs/buds.

1 Remove the test strip guide cover to clean it. (Use your thumbnail to open the cover of the test strip guide by pressing its front edge upward.) Move the cover safely away from the meter. Then rinse the cover with warm water or wipe it clean using the solutions recommended above. Let the test strip guide cover dry **for at least 10 minutes** before re-attaching it.

2 Hold the meter upright with the test strip guide facing down.

- Clean the easily accessible white areas with a moistened cotton swab/bud.
- Ensure the swab/bud is only damp, not wet. Wipe away residual moisture and fluids.

NOTICE **Damage to the instrument**

- Ensure that no liquid enters the meter. If moisture enters the meter, it may cause malfunction of the instrument.
- Do not insert any objects in the test strip guide. Doing so may damage the electrical contacts behind the test strip guide.

On completion of cleaning:

3 With the cover off, let the test strip guide dry for **at least 10 minutes.**

4 After this time, re-attach the test strip guide cover to the housing. Make sure that the cover is properly closed. You will hear it snap into place.

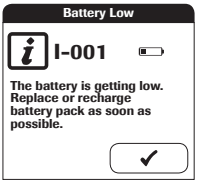
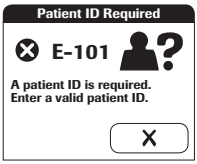
10 Troubleshooting

The CoaguChek XS Plus meter continually checks its systems for unexpected and unwanted conditions. These may arise for technical reasons (defective components or consumables, environmental factors) or due to handling and procedure errors.

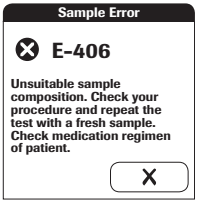
Depending on the circumstances, a message may appear on the display of the meter. These messages are marked with an icon, either for a status message, or for an error message. All messages displayed by the system are accompanied by a description of the error and a possible solution.

Take the action suggested on screen to resolve the problem. If the error disappears, you may continue using the meter as desired. If the problem persists, contact Roche (see page 137).

The two different message types are illustrated below:

Message	Description
I-001: Battery Low	
	**Status message** Touch ✓ to proceed with the next step.
E-101: Patient ID Required	
	**Error message** Touch ✗ to exit this message. Perform the suggested step(s) to solve the problem.

E-406: Sample Error


Sample Error
E-406
Unsuitable sample composition. Check your procedure and repeat the test with a fresh sample. Check medication regimen of patient.
X

Error message

Touch X to exit this message. Perform the suggested step(s) to solve the problem.

Additional information on Error 406

Power the meter off and remove the test strip. Repeat the measurement using a new test strip and blood taken from a new puncture site at the tip of another finger. Do not touch or remove the test strip when a test is in progress.

Note on Error 406: The CoaguChek XS PT Test strip may be used for patients under a combination therapy of oral anticoagulants plus heparin injections. For maximum heparin concentrations which do not interfere with the test, refer to the package insert. Under no circumstances, however, should heparinized capillary tubes be used for sample application. If capillary tubes are used, use only the dedicated CoaguChek capillary tubes. Be sure to apply the blood drop to the test strip within **15 seconds** of lancing the fingertip. In rare cases, patients with long clotting times (> 8 INR; < 5% Quick) may receive an “Error 406” message on the meter display. If this error message appears again when the test is repeated, the result must be checked using another method.

Errors and unusual behavior without error messages

Some conditions may arise that have no associated error or status message.

Message	Description
No message or unusual behavior	
Meter display does not power on	■ Wait 10 seconds and try powering on the unit again. ■ Check that the meter has power. • If you are using the external power adapter, is it connected properly to the meter? Or: • Place the meter in the Handheld Base Unit. Or: • If you are using the Handheld Battery Pack, is it properly installed in the meter?
Meter displays an unexpected result	Refer to the package insert for the test strips.
Automatic shutdown	
	The meter powers off after a configurable time without activity (e.g., pressing a key, touching the screen) to conserve energy. Reactivate the meter/screen as described in the following:
Shutdown after time specified by system administrator (default is 5 minutes, configurable by system administrator)	■ Press the On/Off button of the meter.

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11 General Product Specifications

Technical data

Temperature range	+15 °C to +32 °C (59 °F to 90 °F)
Relative humidity	10 to 85% (no condensation)
Maximum altitude	4300 m (14,000 feet)
Position	Place the meter on a level, vibration-free surface or hold it so it is roughly horizontal.
Measuring range	%Q: 120 – 5 SEC: 9.6 – 96 INR: 0.8 – 8.0
Memory	2000 patient and 500 QC results with date and time 60 code chip records Operator lists up to 5000 Operator IDs with corresponding 2nd ID (e.g., Operator Name) Patient lists up to 4000 Patient IDs with corresponding 2nd and 3rd Patient IDs (e.g., name, date of birth)
Interface	Infrared interface, LED/IRED Class 1
Battery operation	4 x 1.5 V batteries type AA or special rechargeable battery pack for the CoaguChek XS Plus meter
Power connection	Power supply adapter: Input: 100-240 V / 50-60 Hz / 400 mA Output: 7.5 V DC / 1.7 A
Number of tests per set of batteries	Approx. 80 tests (approx. 60 tests per charge cycle when the rechargeable battery pack is used)
Safety class	III
Automatic power-off	Programmable 1 … 60 minutes
Dimensions	185 x 89 x 42 mm
Weight	311 g (without batteries)

Sample material

Sample type	Capillary whole blood or non-anticoagulated venous whole blood.
Sample size	At least 8 µL
Interactions	Refer to test strip package insert

Storage and transport conditions

Temperature range Meter (without batteries)	–25 °C to +70 °C (-13 °F to +158 °F)
Temperature range Meter (with batteries)*	–10 °C to +50 °C (+14 °F to +122 °F)
Relative humidity	10 to 85 % (no condensation)

* At temperatures above +50 °C/122 °F the batteries could leak and damage the meter. At temperatures below -10 °C/+14 °F the batteries do not have enough power to keep the internal clock functioning.

Further Information

Ordering

Please contact Roche Diagnostics Customer Service at 1-800-428-4674.

Item	Description	Remarks
CoaguChek XS PT Test	2 x 24 test strips	04625315160
CoaguChek XS Pro PT Controls	Optional liquid controls for the CoaguChek XS Plus/XS Pro systems	04625382160
CoaguChek Capillary Tubes/Bulbs	Capillary tubes	11621173001
Handheld Battery Pack	Rechargeable battery pack	04805640001
Handheld Base Unit Kit	Handheld Base Unit and Operator's Manual	04805658160

Reagents and solutions

Supplies are available through Roche Diagnostics. Contact your local Roche representative.

Product limitations

Please read the information in the package insert supplied with the test strips for detailed product data and limitations.

Repairs

Please note that repairs and other modifications to the meter may only be performed by persons authorized by Roche.

Information about software licenses

This product incorporates software that is under license from General Public License (GPL). The source code of this software can be requested on a standard data exchange medium from the manufacturer at the following address:

Roche Diagnostics GmbH
Sandhofer Str. 116
68305 Mannheim, Germany

The GPL licensing conditions are printed below (in English only for legal reasons): GPL, Version 2, June 1991.

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12 Warranty

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13 Appendix

Contact Roche

For all questions about the CoaguChek XS Plus system that are not answered in this manual, contact your Roche representative or call Technical Service 24/7/365 at 1-800-428-4674 or visit us online at www.poc.roche.com

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14 Supplement for Observed Test Sequence

Observed Test Sequence (OTS)

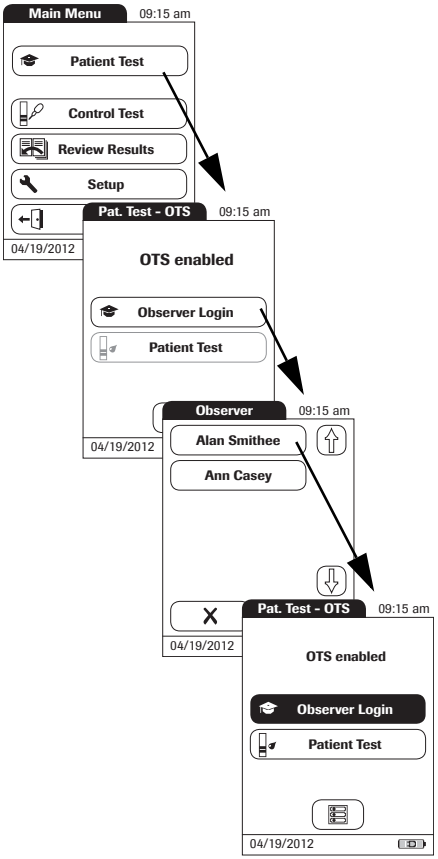
> *Observed Test Sequence* options can only be configured using a DMS. The availability of electronic configuration options will thus vary according to the data management software utilized by your institution. Consult your system administrator.

The *Observed Test Sequence** (OTS) function allows an observer (supervisor) to assess and record an operator's performance (e.g., for recertification purposes). The observer monitors an operator during a test to check that the test is being performed according to the recommended procedures. He/she then evaluates the performance and passes or fails the operator. This assessment is saved together with the test result and any desired comments.

*Note: This feature comes "disabled" on the meter system.

Using the OTS function

A request for an Observed Test Sequence comes from the DMS. The presence of the icon on the *Patient Test* button indicates a pending OTS request.



Observer:

1 Touch **Patient Test**.

In the *Pat. Test -OTS* menu, the **Patient Test** button is grayed out (disabled) until the observer has logged in.

2 Touch **Observer Login**.

3 Wait until the observer list is displayed.

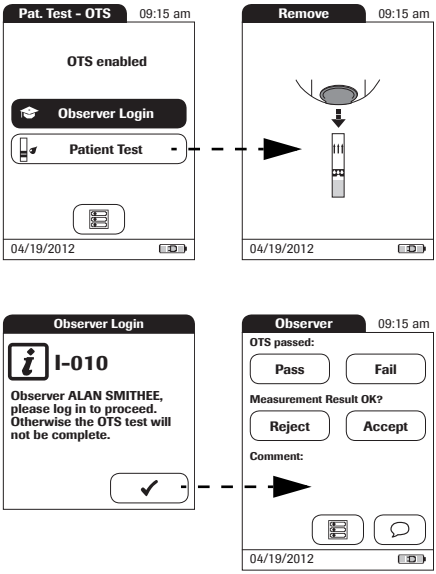
4 Select your observer ID by touching the corresponding button.

Only operators with OTS observer rights are listed in the Observer Login list.

5 Enter the (optional) password.

6 After you enter your password, touch ✓ to log in. The *Pat. Test - OTS* menu is displayed again. The **Patient Test** button is now active.

7 Hand the meter to the operator who can now perform the patient test under supervision.



Operator:

1 Touch **Patient Test**.

Perform the patient test as usual. Once the test is completed, the observer has to complete the next steps.

2 Hand the meter back to the observer.

Observer:

3 Touch ✓ to log in again.

4 After you enter your password, touch ✓ to proceed with the assessment.

5 Assess the operator's performance by touching **Pass** or **Fail**.

6 Assess the test result by touching **Accept** or **Reject**.

7 Touch 💬 to add a comment.

8 Touch ✓ to return to the *Pat. Test - OTS* screen.

The OTS information is saved together with the test result.

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Notes

Notes

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